# COPY -Application NorthCrest Medical Ctr.

CN1504-013

			400	
1.	Name of Facility, Agency, or Institution	<u>on</u>	(2) (2) (2)	
	NorthCrest Medical Center			
	Name			Dohortoon
	100 NorthCrest Drive Street or Route			Robertson County
	Springfield		TN	37172
	City	<del></del> :	State	Zip Code
2.	Contact Person Available for Respon	ses to Qu	<i>lestions</i>	*
	Kim Harvey Looney		Attorney	
	Name		Title	e
	Waller Lansden Dortch & Davis LLP			@wallerlaw.com il address
	Company Name 511 Union Street; Suite 2700	Nashville		37219
	Street or Route	City	State	Zip Code
	Attorney		615-850-8722	615-244-6804
	Association with Owner		Phone Number	Fax Number
3.	Owner of the Facility, Agency or Insti	tution		
	8			
	NorthCrest Medical Center			615-384-1501
	Name			Phone Number
	100 NorthCrest Drive			Robertson
	Street or Route		TNI	County 37172
	Springfield City		TN State	Zip Code
	Oity		Oldio	2.p 0000
4.	Type of Ownership of Control (Check	One)		
	A. Sole Proprietorship		Government (State	
	B. Partnership		or Political Subdivisi	on)
	C. Limited Partnership D. Corporation (For Profit)		Joint Venture Limited Liability Con	nany
	E. Corporation (Not-for-Profit) X		Other (Specify)	

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

Response: Please see corporate documents included as Attachment A-4.

5.	Name of Management/Operating	g Entity (If	App	licable)		
	N/A					
	Name					Vi
	Street or Route				County	
	City			State	Zip Code	-
	PUT ALL ATTACHMENTS AT T REFERENCE THE APPLICABLI	HE END OF E ITEM NUN	TH IBE	E APPLICATION IN OR R ON ALL ATTACHME	RDER AND NTS.	
6.	Legal Interest in the Site of the	Institution	(Ch	eck One)		
	<ul><li>A. Ownership</li><li>B. Option to Purchase</li><li>C. Lease of Years</li></ul>	<u>X</u> 		Option to Lease Other (Specify)	-	
	PUT ALL ATTACHMENTS AT TREFERENCE THE APPLICABLE Response: Please see copy of or	E ITEM NUN	/IBE	R ON ALL ATTACHME	RDER AND INTS.	
7.	Type of Institution (Check as ap	propriater	nor	e than one response m	ay apply)	
	A. Hospital (Specify)  B. Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty C. ASTC, Single Specialty D. Home Health Agency E. Hospice F. Mental Health Hospital G. Mental Health Residential Treatment Facility H. Mental Retardation Institutional Habilitation Facility (ICF/MR)	<u>X</u>	I. J. K. L. M. N.	Nursing Home Outpatient Diagnostic Of Recuperation Center Rehabilitation Facility Residential Hospice Non-Residential Metha Facility Birthing Center Other Outpatient Facilit (Specify) Other (Specify)	Center	
8.	Purpose of Review (Check) as a	ppropriate	mo	re than one response r	nay apply)	
	<ul> <li>A. New Institution</li> <li>B. Replacement/Existing Facility</li> <li>C. Modification/Existing Facility</li> <li>D. Initiation of Health Care Service as defined in TCA § 68-11-1607(4) (Specify) PET Services</li> <li>E. Discontinuance of OB Services</li> <li>F. Acquisition of Equipment</li> </ul>	  X 		Change in Bed Comple [Please note the type of by underlining the appropriate of the second complete of the second	of change copriate ecrease, on,	

9.	Bed Complement Data  Please indicate current and proposed of Response: Not applicable.	distributi	on and ce	rtificatio	n of facili	
		Currer	it Beds	Staffed	Beds	TOTAL Beds at
		Licensed	*CON	Beds	Proposed	Completion
	A. Medical					
	B. Surgical			13		
	C. Long-Term Care Hospital					
	D. Obstetrical				-	
	E. ICU/CCU			-		
	F. Neonatal				:	-
	G. Pediatric			-		-
	H. Adult Psychiatric				)	-
	I. Geriatric Psychiatric					-
	J. Child/Adolescent Psychiatric			-	×	
	K. Rehabilitation					-
	L. Nursing Facility (non-Medicaid Certified)					
	M. Nursing Facility Level 1 (Medicaid only)					
	N. Nursing Facility Level 2 (Medicare only)					
	O. Nursing Facility Level 2					7
	(dually certified Medicaid/Medicare)					
	P. ICF/MR					-
	Q. Adult Chemical Dependency					
	R. Child and Adolescent Chemical					
	Dependency		·			
	S. Swing Beds			-		
	T. Mental Health Residential Treatment	<del></del>				-
	U. Residential Hospice					
	TOTAL					· · · · · · · · · · · · · · · · · · ·
	*CON-Beds approved but not yet in se	ervice				
40	Medicare Provider Number 4400	165				
10.						
	Certification Type <u>Hos</u>	pitai				
11.	Medicaid Provider Number Certification Type  0400 Hos	065 pital				
40	If this is a new facility, will certification	he sour	ht for Mod	licare er	nd/or Med	icaid?
12.	Response: N/A	i be soug	ILL IOL MICC	ilcale al	id/or ivied	ilcaia:
13.	Identify all TennCare Managed Care O	rganizati	ons/Rehav	ioral He	alth Orga	nizations
13.	(MCOs/BHOs) operating in the propos treatment of TennCare participants? ye	ed servid	e area. W	/ill this p	roject inv	olve the es, please
	identify all MCOs/BHOs with which the Response: The applicant has contracts	applica	nt has cor	tracted	or plans t	to contract.
	United Healthcare Community Plan and Te	nnCare S	elect.	.555. 7		,
	Discuss any out-of-network relationsh Response: N/A	ips in pla	ace with M	ICOs/BH	Os in the	area.

NOTE: Section B is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project. Section C addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.

# SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

Response: Please see Executive Summary included as Attachment B-I.

- II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.
  - Describe the construction, modification and/or renovation of the facility (exclusive of Α. major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

If the project involves none of the above, describe the development of the proposal.

Response: NorthCrest Medical Center is a 109-bed non-profit community hospital located in Springfield, Robertson County, just off U.S. Hwy. 431, approximately 30 miles north of Nashville. It serves a rural population. NorthCrest Medical Center is the only hospital in Robertson County. NorthCrest has been recognized each of the last four (4) years as a Top Performer by the Joint Commission on certain key quality measures including heart attack, heart failure, pneumonia and surgical care.

It has also received a Hospital Safety Score from the Leapfrog Group of an A - less than 40% of the hospitals in Tennessee received an A score.

It seeks to offer mobile PET/CT services on a pad that is already in existence on its campus. The pad was built during the original construction of the replacement facility, which opened in late 1995. When the facility opened, MRI services were provided by a mobile unit which utilized this pad location. The pad is located at the rear of the main hospital. The location of the pad is identified on the plot plan of the hospital campus, which is included in <a href="https://example.com/Attachment B-III-A">Attachment B-III-A</a>.

NorthCrest is part of the Vanderbilt Health Affiliated Network ("VHAN"), which has enabled it to expand some of its service lines, including oncology. As part of the affiliation, three (3) Vanderbilt oncologists provide services in an MOB on NorthCrest's campus from 08:30-5:00 Monday thru Friday. Shortly after the Vanderbilt oncologists began practicing in Springfield, NorthCrest contracted with Alliance Healthcare Services ("Alliance") to have a mobile PET/CT scanner provide services to patients in Robertson County. NorthCrest provided the services from approximately September 2013 to February 2015. Neither NorthCrest nor Alliance realized that NorthCrest needed a CON to implement PET services. In March, as soon as it realized its error, NorthCrest immediately discontinued the service and made plans to file a CON at the earliest opportunity.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

Response: Not applicable.

SQUARE FOOTAGE AND COST PER SQUARE FOOTAGE CHART

	Existina	_		Proposed	Prop	Proposed Final Square Footage		Propo	Proposed Final Cost/ SF	
A. Unit / Department	Location	SF	Location	Location	Renovated	11 1	Total	Renovated	New	Total
										Manager Parket
									S. S	
B. Unit/Depart. GSF Sub-Total										
C. Mechanical/										
Electrical Gor		100								
D. Circulation/ Structure GSF		400000								
E. Total GSF		200								
Jane 1914 - Anna Pro-Co	oldoci									

Response: Not applicable,

- C. As the applicant, describe your need to provide the following health care services (if applicable to this application):
  - 1. Adult Psychiatric Services
  - 2. Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
  - Birthing Center
  - 4. Burn Units
  - 5. Cardiac Catheterization Services
  - 6. Child and Adolescent Psychiatric Services
  - 7. Extracorporeal Lithotripsy
  - 8. Home Health Services
  - 9. Hospice Services
  - 10. Residential Hospice
  - 11. ICF/MR Services
  - 12. Long-term Care Services
  - 13. Magnetic Resonance Imaging (MRI)
  - 14. Mental Health Residential Treatment
  - 15. Neonatal Intensive Care Unit
  - 16. Non-Residential Methadone Treatment Centers
  - 17. Open Heart Surgery
  - 18. Positron Emission Tomography
  - 19. Radiation Therapy/Linear Accelerator
  - 20. Rehabilitation Services
  - 21. Swing Beds

Positron emission tomography (PET) has become an essential tool in detecting cancer throughout the body. A PET scan is very different from an ultrasound, X-ray, MRI, or CT. Unlike these imaging technologies which merely confirm the presence of a mass, a PET scan can distinguish between benign and malignant disorders. A PET scan can detect abnormalities in cellular activity, generally before there is any anatomical change. PET is able to diagnose disease before structural changes become detectable with anatomical imaging techniques, potentially improving the prognosis. PET scans allow doctors to detect abnormalities in glucose metabolism, which is a hallmark of cancer cells. PET scans assist in the diagnosis and staging of cancer. PET helps avoid the expense and pain of removing benign nodules, as well as invasive biopsy procedures to determine malignancy. Reports in the scientific literature find that, in some tumors, PET correctly identifies detected lesions 95% of the time. Because PET can survey the whole body, PET can identify distant, occult metastases that may affect the course of treatment and therefore change patient management. PET scans can also be used to determine if treatment has destroyed all of a patient's cancer. PET is also beginning to play a crucial role in bringing about individualized cancer therapy, with doctors using one or more PET tracers to help determine if a particular type of cancer will respond to a particular therapy before therapy begins or soon after it is started.

The applicant proposes to initiate PET services through a mobile service, using a PET/CT scanner. The oncology services that are provided to residents of Robertson County have increased in recent years. In addition to physicians from Tennessee Oncology, since NorthCrest became a member of the VHAN, physicians from Vanderbilt also provide oncology services in Robertson County. As stated previously, NorthCrest initiated PET services through the use of a mobile PET/CT scanner in late 2013 without obtaining the

proper CON approval, but discontinued those services as soon as it realized its error. During the time period that NorthCrest was providing PET services through a mobile PET/CT scanner, from September 2013 to 2015, 227 scans were performed, with an average of 8 per month. The addition of a second day of operation per week will greatly increase access to and use of the PET scanner, according to area referring physicians.

The PET/CT scanner is a good option because in addition to having CT and PET standalone capabilities, it uses the CT images to correct for non-uniform attenuation of the PET images and it uses integrated CT and PET images to localize emission activity in the patient anatomy. The PET/CT scanner has capabilities for imaging all available PET tracers and CT contrast agents and can provide inherently registered anatomical and functional information via an integrated user interface.

As reimbursement has changed and lengths of stay for inpatient services have decreased in recent years, the inpatient services provided by NorthCrest have decreased or remained flat. In order for NorthCrest to remain financially viable it has worked hard to reduce its expenses and to increase the services provided on an outpatient basis. The ability to add PET services to the array of outpatient services offered will assist patients in receiving quality care close to home, as well as allow NorthCrest to continue to increase the outpatient services it provides, which will help alleviate the financial burden on a sole community, rural, non-profit hospital provider.

D. Describe the need to change location or replace an existing facility.

Response: Not applicable.

- E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:
  - 1. For fixed-site major medical equipment (not replacing existing equipment):
    - a. Describe the new equipment, including:
      - Total cost ;(As defined by Agency Rule).
      - 2. Expected useful life;
      - 3. List of clinical applications to be provided; and
      - 4. Documentation of FDA approval.

Response: Not applicable.

b. Provide current and proposed schedules of operations.

Response: Not applicable.

- 2. For mobile major medical equipment:
  - a. List all sites that will be served;
  - b. Provide current and/or proposed schedule of operations;
  - c. Provide the lease or contract cost.

- d. Provide the fair market value of the equipment; and
- e. List the owner for the equipment.

Response: The applicant proposes to lease a mobile PET/CT scanner to operate at its hospital location. The applicant proposes to provide the service up to three (3) days per week in order to meet the needs of service area residents. The schedule of operation is anticipated to be two (2) days per week when the service is implemented - on Tuesday and Thursday from 7:30 a.m. to 12:30 p.m. The cost of the lease has not yet been determined. In both the Project Costs Chart and the Projected Data Chart, the applicant used \$3,090 per five (5) hour half day of service with an hourly overtime rate of \$300 per hour and a charge of \$150 per radiopharmaceutical dose. The fair market value of the equipment is \$225,000. The owner of the equipment is Alliance Healthcare Services, Inc. ("Alliance").

Alliance delivers a provider's mobile system on a regular schedule that is also flexible enough to grow as NorthCrest's scan volume increases. Along with the equipment and transportation, Alliance provides qualified technologists, maintenance, marketing, and referring physician education. The logistics team also works closely with each new customer to assist with site development and electrical planning. Alliance can also perform a diagnostic evaluation to measure the overall level of customer satisfaction and determine when it may make sense to expand the level of service or consider building a fixed site.

3. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

Response: The applicant intends to lease the equipment. Please see attached draft lease included as Attachment B-II-E(3).

- III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:
  - Size of site (in acres);
  - 2. Location of structure on the site; and
  - Location of the proposed construction.
  - 4. Names of streets, roads or highway that cross or border the site.

Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

**Response:** Please see <u>Attachment B-III-A</u>, for an attached copy of the plot plan identifying the NorthCrest campus. The location of the mobile pad is included on the plot plan. The hospital occupies a site of approximately thirty seven (37) acres, on U.S. Hwy. 431.

(B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

**Response:** The site is easily accessible to service area residents as it is located midway between I65 and I24 on U.S. Hwy. 431.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

NOTE: <u>DO NOT SUBMIT BLUEPRINTS</u>. Simple line drawings should be submitted and need not be drawn to scale.

**Response:** Please see <u>Attachment B-IV</u> for a diagram of the mobile PET/CT unit.

- V. For a Home Health Agency or Hospice, identify:
  - 1. Existing service area by County;
  - 2. Proposed service area by County;
  - 3. A parent or primary service provider;
  - 4. Existing branches; and
  - 5. Proposed branches.

Response: Not applicable.

# SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. Please type each question and its response on an 8 1/2" x 11" white paper. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

#### **QUESTIONS**

#### NEED

- 1. Describe the relationship of this proposal toward the implementation of the State Health Plan and <u>Tennessee's Health: Guidelines for Growth</u>.
  - a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.

**Response:** Please see response to the CON review standards and criteria for PET included below.

b. Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c)

Response: Not applicable.

#### CON REVIEW STANDARDS AND CRITERIA

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

Response: The table below identifies the type of procedures with an estimate of the number that will be performed in the first 3 years of operation. In addition to its uses for cancer detection, the scanner is used by neurologists, pulmonologists, general surgeons, and vascular surgeons.

Estimated Utilization for PET by Patient Clinical Diagnoses Category (ICD-9)

	ICD-9 code	2015	2016	2017
Total # of Procedures		475	573	602
Stroke	434.91	38	46	48
Alzheimer	331	33	40	42
Parkinson's	332	33	40	42
Breast	174	95	115	121
Colon/Rectum	153	86	103	108
Lung/Bronchus	162	114	137	145
Prostate	185	76	92	96
Total		475	573	602

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

Response: NorthCrest anticipates initiating the PET service at least 2 days per week. The applicant proposes 475 scans the first year of operation, or 238 per day, gradually growing to over 300 per day of use in the third year of operation. NorthCrest feels that these estimates are conservative and has based them in part on the number of scans it performed prior to its discontinuance of the service as well as discussions with the oncologists who practice in Robertson County. The oncologists are very supportive of the necessity to provide PET services in Robertson County. They feel it is necessary to provide the service more than one day per week in order that patients in Robertson County may receive the service as close to home as possible, in the least restrictive setting. The ability to receive the service in

Robertson County means less disruption to both the patient's work schedule as well as any family members or other support/caregivers who are assisting in the receipt of medical services by the patient.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

**Response:** The service area for NorthCrest Medical Center is Robertson County. The hospital location is accessible to more than 75% of the service area's population.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

**Response:** The provision of a mobile unit will allow NorthCrest an orderly progression into use and potential expansion of the services provided without a large capital expenditure. There is no more cost effective manner in which to provide this beneficial service. Approximately 40% of the providers in Tennessee who currently provide PET services do so with a mobile scanner based on the HSDA Equipment Registry for 2014.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

Response: NorthCrest has established relationships with both Vanderbilt-Ingram Cancer Center and Tennessee Oncology. Both Vanderbilt-Ingram Cancer Center and Tennessee Oncology have medical oncologists available to the residents of Robertson County, 08:30 a.m.-5:00 p.m., Monday-Friday with a medical oncologist seeing patients, and accepting appointments each day. Both provider groups have indicated that they prefer to have their Robertson County patients receive services in Robertson County and if the PET service is provided a minimum of two (2) days per week in Robertson County, then they will send more patients to the local PET scanner rather than sending them to Nashville for their scan.

In addition to its uses for cancer patients, neurologists, pulmonologists, general surgeons and vascular surgeons are also expected to use the PET scanner for their patients. Letters of support are included from some of these physicians in the Letters of Support section.

A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

Response: Not applicable. There are currently no PET scanners in Robertson County.

- The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
  - a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

**Response:** Please see attached letter from the FDA certifying that the proposed PET scanner has been approved for clinical use, included as <u>Attachment C-Need-Review</u> Standards and Criteria-6-a.

b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

**Response:** The proposed mobile PET unit will offer the proposed PET procedures in a physical environment that conforms to applicable federal standards and manufacturer's specifications as well as any licensing requirements.

c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

**Response:** NorthCrest will comply with all required provisions for the rendering of emergent care for patients receiving services within the PET unit. A standard crash cart stocked with the appropriate equipment and medications will be available in the PET unit. Staff is trained to handle emergency situations. Should transport of the patient be required, the patient would be transported to the emergency room, which is approximately 100 yards from the unit.

d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

**Response:** The applicant will perform utilization review to ensure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology, Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners – whichever is appropriate given the setting – is required. Those qualified physicians that provide interpretation services should have additional

documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

**Response:** NorthCrest contracts with Southern Radiology Associates ("SRA") for diagnostic interpretation of all exams performed for existing imaging services and for medical director services. Dr. Wes Brewer, board certified Radiologist, is the Medical Director and will serve in that capacity for the proposed PET/CT services as well. Through our contractual agreement radiopharmaceuticals are provided and handled by the mobile service provider. Please see the contractual agreement attached hereto as Attachment C-Need-Review Standards and Criteria-6-e.

f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

Response: Not applicable. The applicant is a hospital.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

**Response:** The applicant will submit data in a timely fashion as requested so that the HSDA may maintain the HSDA Equipment Registry.

- 8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:
  - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

Response: Not applicable.

b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

Response: Not applicable.

c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

Response: Not applicable. NorthCrest is not a safety net or children's hospital.

d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

**Response:** NorthCrest Medical Center contracts with all 4 TennCare MCOs serving Robertson County and its percentage of TennCare patients by revenue is 18 percent. The TennCare MCOs in Robertson County include: Amerigroup, BlueCare, United

Healthcare Community Plan and TennCare Select. The percentage of its patients who are Medicare patients by gross revenue is 43%.

#### STATE HEALTH PLAN

Tennessee Code Annotated Section 68-11-1625 requires the Tennessee Department of Health's Division of Health Planning to develop and annually update the State Health Plan (found at <a href="http://www.tn.gov/finance/healthplanning/">http://www.tn.gov/finance/healthplanning/</a>). The State Health Plan guides the state in the development of health care programs and policies and in the allocation of health care resources in the state, including the Certificate of Need program. The 5 <a href="https://principles.org/">Principles for Achieving Better Health</a> form the State Health Plan's framework and inform the Certificate of Need program and its standards and criteria.

Please discuss how the proposed project will relate to the <u>5 Principles for Achieving Better</u> <u>Health</u> found in the State Health Plan. Each Principle is listed below with example questions to help the applicant in its thinking.

- 1. The purpose of the State Health Plan is to improve the health of Tennesseans.
  - a. How will this proposal protect, promote, and improve the health of Tennesseans over time?

Response: The ability of Robertson County residents to receive such a necessary health care service as a PET scan in Robertson County rather than having to travel to another county to receive the services will contribute both to the promotion and improvement of the health of Robertson County residents. The closest scanners are in Clarksville, Montgomery County, or Nashville, Davidson County, both of which are slightly more than 30 miles away. When patients are able to receive important diagnostic services close to home, they can also begin appropriate treatment potentially in a more timely manner, which can have a positive impact on the health of Robertson County residents. PET helps avoid the expense and pain of removing benign nodules, as well as invasive biopsy procedures to determine malignancy.

b. What health outcomes will be impacted and how will the applicant measure improvement in health outcomes?

Response: The ability to have timely access to a PET scan for Robertson County residents means that patients can receive appropriate cancer treatment based on the outcome of the scan faster than if the patient has to travel to another county to receive the diagnostic test, which could assist in the timely treatment and prognosis of such patients.

c. How does the applicant intend to act upon available data to measure its contribution to improving health outcomes?

Response: NorthCrest anticipates that the physicians who have ordered the scans will review information regarding the health of the patients. As they evaluate the health of their patients, the ability to have a scan close to

home and begin treatment promptly should assist in improving health outcomes of area residents.

- 2. Every citizen should have reasonable access to health care.
  - a. How will this proposal improve access to health care? You may want to consider geographic, insurance, use of technology, and disparity issues (including income disparity), among others.

**Response:** The project will improve access to health care by making PET/CT more physically accessible to patients who are having to leave the service area to obtain PET/CT services, which decreases the burden of both the patient and their support system in travel to receive PET.

b. How will this proposal improve information provided to patients and referring physicians?

Response: This project will improve information provided to patients and referring physicians by providing the service in the community where patients live and the referring physician provides care. A PET scan allows physicians to diagnose and manage cancer more effectively than without it. The information provided by PET scans provides patients, their families, and their physician potentially life-saving information that can help the physician detect and diagnose diseases early and quickly begin treatment.

c. How does the applicant work to improve health literacy among its patient population, including communications between patients and providers?

Response: NorthCrest is committed to enhancing wellness in its community. Education is a key component to wellness. NorthCrest uses several methods in helping to educate its community. Health fairs in the community or at local industries are one method NorthCrest uses to educate individuals. Health fairs allow educational material and screenings to be provided on a one-on-one basis. NorthCrest uses educational booths at popular local events to distribute information to event attendees. NorthCrest provides free local seminars on specific topics that allow participants to interact with experts in that particular field. NorthCrest makes sure to use educational opportunities when patients are in the hospital as either an inpatient or outpatient. NorthCrest also uses direct mail and newspaper advertisement to educate its community on new services and specialties that are available.

NorthCrest uses many methods to communicate with physicians as well. The most important are one-on-one meetings held with the physician and staff in the physician's office. NorthCrest uses monthly and quarterly physician meetings both inside and outside the hospital to communicate, along with using weekly and monthly newsletter. Physicians are who many patients look to for education, so it is extremely important that the physician be in direct communication with the hospital on a regular basis.

For the PET services, Alliance will also provide marketing and referring physician education.

- 3. The State's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the State's health care system.
  - a. How will this proposal lower the cost of health care?

Response: Providing PET/CT services closer to home for NorthCrest Medical Center patients advances efficiency in obtaining care. It results in lower cost partly in less time away from work both for the person receiving the scan and for those persons who are part of their support group, assisting the patient in receiving the necessary diagnostic services and then treatment for their condition.

b. How will this proposal encourage economic efficiencies?

**Response:** Providing PET/CT services closer to home for NorthCrest Medical Center patients advances efficiency in obtaining care. In addition, providing PET through a mobile service is the most cost efficient way to bring this necessary diagnostic tool to Robertson County residents.

c. What information will be made available to the community that will encourage a competitive market for health care services?

Response: NorthCrest will work to ensure that the area residents are familiar with the service offered so that they have a choice in where they receive the service, and since the service is closer to home, it may make the current options a little more competitive.

- 4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.
  - a. How will this proposal help health care providers adhere to professional standards?

Response: The applicant is currently licensed and accredited to offer a full range of diagnostic services, and will make sure that all professional standards are met.

b. How will this proposal encourage continued improvement in the quality of care provided by the health care workforce?

Response: Additional choice will help encourage quality of the service provided. NorthCrest has been recognized as a Top Performer by the Joint Commission each of the last four (4) years on certain key quality measures including heart attack, heart failure, pneumonia and surgical care. It has also received a Hospital Safety Score from the Leapfrog Group of an A-less than 40% of the hospitals in Tennessee received an A score.

5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.\*

a. How will this proposal provide employment opportunities for the health care workforce?

**Response:** Not applicable. The mobile company provides necessary staffing for the PET scanner.

b. How will this proposal complement the existing Service Area workforce?

**Response:** The service area contains no PET service currently. Approval of this proposal will complement the existing services, and its workforce by keeping patients in our community. No additional staff are necessary to provide this important diagnostic service.

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

Response: As with many hospitals, and especially rural, non-profit hospitals, NorthCrest is constantly evaluating how best to meet the health care needs of its patients. Expanding outpatient services to include PET is consistent with that goal and will allow NorthCrest to provide an important diagnostic test option for physicians and patients closer to home.

3. Identify the proposed service area <u>and</u> justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).

**Response:** The service area for NorthCrest Medical Center is Robertson County. Approximately 83 percent of the NorthCrest patients came from Robertson County in 2013, according to the Joint Annual Report. Therefore, a service area of Robertson County is reasonable for the applicant. Please see the service area map attached hereto as Attachment C-Need-3.

4. A. Describe the demographics of the population to be served by this proposal.

Response: As can be seen in the tables below, Robertson County has some patient cohorts that are decreasing, but the population aged 20 and older is expected to increase from 52,068 persons to 57,912 persons, or an increase of 11%, from 2015 to 2019. The median age of persons in Robertson County is almost identical to that of the State, while the median household income in Roberson County is higher than the State, and the percentage of the population in Robertson County that is below the poverty level is lower than that of the State.

# Current and Projected Population Change

Tot	al Proposed Service A	rea of Robertson Coun	ty
Age	2015	2019	% Change
0 to 19	19,369	17,400	(10.2)
20 to 44	20,188	19,716	(2.3)
45 to 64	23,568	28,507	21.0
65 to 74	6,105	7,616	24.8
75 plus	2,207	2,073	(6.1)
Total 65 plus	8,312	9,689	16.6
Total	71,437	75,312	5.4

#### Tennessee

Age	2015	2019	% Change
0 to 19	1,683,742	1,713,807	1.8
20 to 44	2,179,086	2,235,222	2.6
45 to 64	1,773,673	1,811,403	2.1
65 to 74	610,343	684,868	12.2
75 plus	402,594	449,697	11.7
Total 65 plus	1,012,937	1,134,565	12.0
Total	6,649,438	6,894,997	3.7

### **Demographic Information**

1	Service Area Robertson County	State of Tennessee
Age 65+, % Total (PY)	12.7%	16.5%
Median Age	38.1	38.2
Median Household Income	\$52,792	\$44,298
Population % Below Poverty Level	13.0%	17.6%

Source: TDH Population Projections, June 2013; U.S. Census QuickFacts and FactFinder 2

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

Response: As a community-based non-profit acute care hospital, NorthCrest Medical Center currently services these patient populations. NorthCrest understands these patients are often limited in their abilities to travel for health care. This project will assist this patient population by expanding a very important diagnostic health care resource in the community.

Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

**Response:** NorthCrest Medical Center is the sole community provider in Robertson County. There are no unimplemented CONs in Robertson County. PET services are not currently provided in Robertson County.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology <u>must include</u> detailed calculations or documentation from referral sources, and identification of all assumptions.

Response: See utilization charts below.

**Hospital Utilization** 

Year	Occupancy (%)
2012	43%
2013	38%
2014	34%
2015	34%
2016	34%

**PET Projected Utilization** 

Year	Number of Procedures
2015	475
2016	573
2017	602

NorthCrest anticipates initiating the PET service at least 2 days per week. The applicant proposes 475 scans per day the first year of operation, gradually growing to over 300 per day in the third year of operation. NorthCrest feels that these estimates are conservative and has based them in part on the number of scans it performed prior to its discontinuance of the service as well as discussions with the oncologists who practice in Robertson County. The oncologists are very supportive of the necessity to provide PET services in Robertson County. They feel it is necessary to provide the service more than one day per week in order that patients in Robertson County may receive the service as close to home as possible, in the least restrictive setting. The ability to receive the service in Robertson County means less disruption to both the patient's work schedule as well as any family members who are assisting in the receipt of medical services by the patient.

# **ECONOMIC FEASIBILITY**

- 1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.
  - All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)
  - The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.
  - The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.
  - For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.

Response: Please see Project Costs Chart which identifies the costs for the implementation of PET services for NorthCrest Medical Center. No construction is necessary for this project. The pad necessary to provide the mobile service is already in existence. The applicant proposes to lease the necessary equipment to provide the PET service. The costs to do so are reasonable, especially when compared to the cost of a new, fixed PET scanner. To provide a fixed PET scanner would also require NorthCrest to renovate and/or provide new construction to house the PET scanner, thereby increasing the costs of such a project.

# PROJECT COSTS CHART

Α.	Cons	struction and equipment acquired by purchase:	Q.
	1.	Architectural and Engineering Fees	-0-
	2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	\$35,000
	3.	Acquisition of Site	
	4.	Preparation of Site	-0
	5.	Construction Costs	-0
	6.	Contingency Fund	-0-
	7.	Fixed Equipment (Not included in Construction Contract)	-0
	8.	Moveable Equipment (List all equipment over \$50,000)	0-
	9.	Other (Specify)	-0-
B.	Acqu	uisition by gift, donation, or lease:	
	1.	Facility (inclusive of building and land)	-0-
	2.	Building only	-0
	3.	Land only	-0-
	4.	Equipment (Specify) Mobile PET Unit	\$321,360
	5.	Other (Specify) Supplies	\$71,250
C.	Fina	ncing Costs and Fees:	
	1.	Interim Financing	-0-
	2.	Underwriting Costs	-0-
	3.	Reserve for One Year's Debt Service	-0-
	4.	Other (Specify)	-0-
D.	Estin	nated Project Cost (A+B+C)	\$427,610
E,	CON	I Filing Fee	3,000
F	Tota (D+E	Estimated Project Cost	\$430,610

2.	Identif	y the funding sources for this project.
	finance applie	e check the applicable item(s) below and briefly summarize how the project will be ed. (Documentation for the type of funding MUST be inserted at the end of the eation, in the correct alpha/numeric order and identified as Attachment C, omic Feasibility-2.)
	Α.	Commercial loanLetter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
	B.	Tax-exempt bondsCopy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
	C.	General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
	D.	GrantsNotification of intent form for grant application or notice of grant award; or
X	E.	Cash ReservesAppropriate documentation from Chief Financial Officer.
	F.	Other—Identify and document funding from all other sources.
	Resp	onse: Please see letter included as Attachment B-Economic Feasibility-2-E.
3.	compa	ss and document the reasonableness of the proposed project costs. If applicable, are the cost per square foot of construction to similar projects recently approved by ealth Services and Development Agency.
2	deterr used :	onse: The project costs are reasonable. The cost of the lease has not yet been nined. In both the Project Costs Chart and the Projected Data Chart, the applicant \$3,090 per five (5) hour half day of service with an hourly overtime rate of \$300 per and a charge of \$150 per radiopharmaceutical dose. There is no construction for this st.
4.	modification repression complete for the should application application modified application modified repression application application modified repression application application modified repression application application application modified repression application a	lete Historical and Projected Data Charts on the following two pages <u>Po not</u> for the Charts provided or submit Chart substitutions! Historical Data Chart sents revenue and expense information for the last three (3) years for which lete data is available for the institution. Projected Data Chart requests information to two (2) years following the completion of this proposal. Projected Data Chart reflect revenue and expense projections for the <b>Proposal Only</b> (i.e., if the ation is for additional beds, include anticipated revenue from the proposed beds not from all beds in the facility).
	Respe includ	onse: Please see Historical Data Chart for NorthCrest. The Projected Data Chart is ed for the Proposal only, as required by the application.

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

**Response:** The average gross charge is approximately \$3,679, the average deductions are approximately \$2,685, for an average net charge of \$993.

# HISTORICAL DATA CHART

Give information for the last *three* (3) years for which complete data are available for the facility or agency. The fiscal year begins in July (Month).

~g-		, no necal year a egant year	,	Year 2014	Year 2013	Year 2012
A.	l Itili	zation Data (Occupancy)		34%	38%	43%
В.		venue from Services to Patients				
٥.	1.	Inpatient Services		\$65,663,379	\$65,502,379	\$67,649,509
	2.	Outpatient Services		\$130,846,417	\$116,256,943	\$96,217,356
	3.	Emergency Services		\$40,746,905	\$39,454,537	\$38,846,939
	4.	Other Operating Revenue (Specify)		\$2,011,896	\$2,835,642	\$4,056,918
		Gross Ope	erating Revenue	\$239,268,927	\$224,049,501	\$206,770,722
C.	Dec	ductions from Gross Operating Revenu	ie			
	1.	Contractual Adjustments		\$159,446,371	\$141,646,654	\$126,594,917
	2.	Provision for Charity Care		\$5, 556,198	\$5,197,553	\$3,913,834
	3.	Provisions for Bad Debt		\$10,927,452	\$11,560,126	\$9,306,696
		. т	otal Deductions	\$175,930,021	\$158,404,333	\$139,815,447
NE	г ор	ERATING REVENUE		\$63,338,906	\$65,645,168	\$66,955,275
D.	Оре	erating Expenses				
	1.	Salaries and Wages		\$23,472,744	\$26,010,725	\$25,217,785
	2.	Physician's Salaries and Wages				
	3.	Supplies		\$11,826,331	\$12,203,654	\$11,549,902
	4.	Taxes		\$178,271	\$161,767	\$117,138
	5.	Depreciation		\$4,511,798	\$3,992,251	\$4,176,902
	6.	Rent		\$1,096,918	\$996,652	\$892,477
	7.	Interest, other than Capital		-0-	-0-	-0-
	8.	Management Fees:			_	•
		a. Fees to Affiliates		-0-	-0-	-0-
		b. Fees to Non-Affiliates		-0-	-0-	-0-
	9.	Other Expenses – Specify on separa	ate page 12	\$19,098,290	\$20,935,949	\$21,215,248
		Total Ope	rating Expenses	\$60,184,352	\$64,300,998	\$63,169,452
E.	Oth	ner Revenue (Expenses) – Net (Specif	y)	\$583,542	\$1,073,175	\$1,073,175
NE	Т ОР	ERATING INCOME (LOSS)		\$3,738,096	\$2,417,345	\$4,858,998
F.	Cap	pital Expenditures				
	1.	Retirement of Principal		\$2,053,200	\$1,373,000	\$1,318,000
	2.	Interest		\$2,096,321	\$2,144,851	\$2,156,336
		Total Capi	tal Expenditures	\$4,149,521	\$3,517,851	\$3,474,336
NE	т ор	ERATING INCOME (LOSS)		(\$411,425)	(\$1,100,506)	(\$1,384,662)
		APITAL EXPENDITURES				

# PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in July (Month).

in Ju	ıly (№	fonth).	Year 2016	Year 2017
A.	Utili	zation Data (Number of Procedures)	475	573
В.	Rev	venue from Services to Patients		
	1.	Inpatient Services	\$	\$
	2.	Outpatient Services	\$1,747,525	\$2,108,067
	3.	Emergency Services	\$	\$
	4.	Other Operating Revenue (Specify)	\$	\$
		Gross Operating Rev	enue \$1,747,525	\$2,108,067
C.	Dec	ductions from Gross Operating Revenue		
	1.	Contractual Adjustments	\$1,153,367	\$1,391,324
	2.	Provision for Charity Care	\$52,426	\$63,242
	3.	Provisions for Bad Debt	\$69,901	\$84,323
		Total Deduc	tions \$1,275,693	\$1,538,889
NET	OPE	ERATING REVENUE	\$471,832	\$569,178
D.	Оре	erating Expenses		
	1.	Salaries and Wages	\$	\$
	2.	Physician's Salaries and Wages	\$	\$
	3.	Supplies	\$71,250	\$88,529
	4.	Taxes	\$	\$
	5.	Depreciation	\$	\$
	6.	Rent	\$321,360	\$331,001
	7.	Interest, other than Capital	\$	\$
	8.	Management Fees:  a. Fees to Affiliates	\$ \$	\$ \$
	9.	<ul><li>b. Fees to Non-Affiliates</li><li>Other Expenses – Specify on separate page 12</li></ul>	Ψ	Ψ
		Total Operating Expe	nses \$392,610	\$419,529
E.	Oth	er Revenue (Expenses) Net (Specify)	\$	\$
NET		ERATING INCOME (LOSS)	\$79,222	\$149,649
F.	Car	pital Expenditures		
	1.	Retirement of Principal	\$	\$
	2.	Interest	· · · · · · · · · · · · · · · · · · ·	-
		Total Capital Expendi	tures \$	\$
		ERATING INCOME (LOSS) APITAL EXPENDITURES	\$ <u>79,222</u>	\$ <u>149,649</u>

# HISTORICAL DATA CHART-OTHER EXPENSES

OTHER EXPENSES CATEGORIES		Year 2014	Year 2013	Year 2012	
1.	Contract Labor	\$1,477,647	\$1,246,375	\$689,706	
2.	Fringe Benefits	\$6,687,083	\$7,583,973	\$8,367,107	
3.	Medical Specialist	\$650,319	\$646,635	\$1,094,266	
4.	Contract Services	\$4,629,292	\$5,083,451	\$4,793,316	
5.	Maintenance Expense	\$2,393,678	\$2,602,713	\$2,347,169	
6.	Utilities	\$1,337,843	\$,538,128	\$1,552,266	
7.	Insurance	\$523,684	\$483,376	\$589,299	
8.	Other	\$1,398,744	\$1,751,298	\$1,782,119	
	Total Other Expenses	\$19,098,290	\$20,935,949	\$21,215,248	

# PROJECTED DATA CHART-OTHER EXPENSES

OTHER EXPENSES CATEGORIES	Year	Year
1,	\$	\$
2,	e	
3.		
4.		-
5,	-	*
6,	%	-
7.		46
Total Other Expenses	\$	\$

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

Response: Please see the proposed charge schedule for this service.

		Proposed Charge Schedule			
Service Charge Medicare Code CPT		Description	Department Number	Price1	
7730092	78811	Pet limited; chest, head/neck	773	2,973.00	
7730093	78812	Pet skull; base to mid-thigh	773	4,120.00	
7730094	78813	Pet whole body	773	4,120.00	
7730095	78608	Pet brain; metabolic evaluation	773	2,973.00	
7730096	78814	Pet w/ct; chest, head/neck	773	2,973.00	
7730097	78815	Pet w/ct; skull base to mid-thigh	773	5,356.00	
7730098	78816	Pet w/ct; whole body	773	5,356.00	
7730099	78459	Pet myocardial; metabolic eval	773	2,973.00	
7730100	78491	Pet myocardial; perfusion, single study;	773	2,973.00	
7730101	78492	Pet myocardial; perfusion; multiple study	773	2,973.00	
7730102	A9552	Fdg, per dose	773	465.00	

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Response: Please see Medicare charge schedule by CPT code below.

Medicare Fee Schedule						
	HCPCS Code	Short Descriptor	SI	APC	Relative Weight	Payment Rate
78811	78811	Pet image Itd area	S	0308	17.3409	\$1,286.23
78812	78812	Pet image skull-thigh	S	0308	17.3409	\$1,286.23
78813	78813	Pet image full body	S	0308	17.3409	\$1,286.23
78814	78814	Pet image w/ct lmtd	S	0308	17.3409	\$1,286.23
78815	78815	Pet image w/ct skull-thigh	S	0308	17.3409	\$1,286.23
78816	78816	Pet image w/ct full body	S	0308	17.3409	\$1,286.23
78608	78608	Brain imaging (pet)	S	0308	17.3409	\$1,286.23
78459	78459	Heart muscle imaging (pet)	S	0308	17.3409	\$1,286.23
78491	78491	Heart image (pet) single	S	0308	17.3409	\$1,286.23
78492	78492	Heart image (pet) multiple	S	0308	17.3409	\$1,286.23

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

**Response:** NorthCrest anticipates a net operating income of \$79,222 the first year of operation, increasing to \$149,649 the second year of operation.

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

**Response:** NorthCrest anticipates positive cash flow the first year of operation.

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

Response: NorthCrest anticipates 18% TennCare/Medicaid, 43% Medicare, 3% charity care and 4% bad debt based on gross revenues. The TennCare net operating revenue is projected to be \$84,929 in 2015 and the Medicare net operating revenue is anticipated to be \$202,887.

10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.

Response: Please see copy of balance sheet and income statement and the most current audited financial statements included as Attachment C, Economic Feasibility-10.

- 11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:
  - a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

Response: There are no less costly, or effective or efficient ways to provide a diagnostic tool such as PET than through a mobile service. The costs of providing such a service on a mobile basis allow a provider who needs the service, but cannot justify or afford it on a full-time basis the ability to provide a necessary diagnostic tool to meet the health care needs of its patient population.

b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

**Response:** This project does not involve new construction. The applicant proposes to lease a mobile PET/CT scanner and operate it on the hospital campus on an existing pad for mobile equipment.

# CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

**Response:** As the sole hospital provider, NorthCrest has a good working relationship with all existing health care providers in the community.

Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

Response: There are only positive effects. There are no existing providers of PET services in Robertson County. PET services are an essential tool in detecting cancer throughout the body. Unlike other imaging technologies which merely confirm the presence of a mass, a PET scan can distinguish between benign and malignant disorders. PET helps avoid the expense and pain of removing benign nodules, as well as invasive biopsy procedures to determine malignancy. The initiation of this service in Robertson County will allow more timely access to a necessary diagnostic tool and increase outcomes for its service area residents. In addition to its uses for cancer detection, the scanner is used by neurologists, pulmonologists, general surgeons, and vascular surgeons.

The oncologists and other physicians providing services in Robertson County have indicated that they would prefer to send their patients to a location in Robertson County to receive PET services and the initiation of this service two days a week will allow them to do so for most patients, without unduly delaying diagnosis and treatment of those patients.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

Response: Along with the equipment and transportation, Alliance provides qualified technologists for the staffing of the PET scanner. NorthCrest is not responsible for the provision of any clinical staff.

Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

Response: Not applicable.

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

**Response:** The applicant is a licensed provider and understands all requirements of the State of Tennessee for the provision of this PET service.

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

Response: Not applicable.

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.

**Response:** The applicant has reviewed and understands all licensure requirements of the Department of Health as well as any applicable Medicare requirements for the provision of this service.

(b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Licensure:

**Response:** NorthCrest Medical Center is licensed by the Tennessee Department of Health.

Accreditation:

Response: NorthCrest Medical Center is accredited by The Joint Commission.

(c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

Response: NorthCrest is in good standing with and all licensing, certifying and accreditation agencies. A copy of the current license and Joint Commission accreditation are included as <u>Attachment C- Contribution to the Orderly</u> Development of Health Care -7(c).

(d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

Response: The most recent license/certification inspection report is included as Attachment C-Contribution to the Orderly Development of Health Care-7-(d).

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

Response: Not applicable.

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

Response: Not applicable...

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

**Response:** If approved, NorthCrest will provide the HSDA with the required information.

#### PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

Please see attached copy of the publication from *The Robertson County News*, showing publication occurred on April 8, 2015.

#### DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

- 1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
- 2. If the response to the preceding question indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph, please state below any request for an extended schedule and document the "good cause" for such an extension.

Form HF0004 Revised 02/01/06 Previous Forms are obsolete

# PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in TCA § 68-11-1609(c): July 2015

Assuming the CON approval becomes the final agency action on that date; indicate the number of days from the above agency decision date to each phase of the completion forecast.

		DAVE	<b>Anticipated Date</b>
<u>Phase</u>		DAYS REQUIRED	(MONTH/YEAR)
1,,	Architectural and engineering contract signed		12 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
2	Construction documents approved by the Tennessee Department of Health	<u> </u>	
3.	Construction contract signed		:
4.	Building permit secured	·	
5.	Site preparation completed		3-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1
6.	Building construction commenced		-
7.	Construction 40% complete		
8.	Construction 80% complete	-	s <del></del>
9.	Construction 100% complete (approved for occupancy		
10.	*Issuance of license	N/A	N/A
11.	*Initiation of service	15 days	August 2015
12.	Final Architectural Certification of Payment	-	-
13.	Final Project Report Form (HF0055)	<u>45 days</u>	September 2015

For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

# <u>AFFIDAVIT</u>

# STATE OF TENNESSEE COUNTY OF DAVIDSON

Kim Harvey Looney	, being first	duly sworn,	says	that he/s	she is	the app	olicant
named in this application or	his/her/its lawful	agent, that	t this	project v	vill be	complet	ed in
accordance with the application	n, that the applica	nt has read	the dir	ections to	this a	pplicatio	n, the
Rules of the Health Services a	and Development	Agency, and	d T.C.	A. § 68-1	1-1601	, et seq	., and
that the responses to this app	lication or any oth	ner questions	s deen	ned appro	opriate	by the H	lealth
Services and Development Age	ency are true and				^		
			1	01	()		

Sworn to and subscribed before me this 13th day of April, 2015 a Notary (Month) (Year)

Public in and for the County/State of Tennessee.

My commission expires, \( \)

(Year)

# Attachment A-4 Organizational Documents



# STATE OF TENNESSEE Tre Hargett, Secretary of State

Division of Business Services
William R. Snodgrass Tower
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

WALLER LANSDEN DORTCH & DAVIS LLP STE 2700 511 UNION ST NASHVILLE, TN 37219-1791

Request Type: Certified Copies

Request #:

157543

Issuance Date:

03/27/2015

Copies Requested: 1

**Document Receipt** 

Receipt #: 001943886

Filing Fee:

\$20.00

Payment-Check/MO - WALLER LANSDEN DORTCH & DAVIS LLP, NASHVILLE, TN

\$20.00

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that NORTHCREST MEDICAL CENTER, Control # 198302 was formed or qualified to do business in the State of Tennessee on 12/18/1987. NORTHCREST MEDICAL CENTER has a home jurisdiction of TENNESSEE and is currently in an Active status. The attached documents are true and correct copies and were filed in this office on the date(s) indicated below.

Tre Hargett Secretary of State

Processed By: Sheila Keeling

The attached document(s) was/were filed in this office on the date(s) indicated below:

Reference #	Date Filed	Filing Description
731 00395	12/18/1987	Initial Filing
1066-1819	12/06/1988	Articles of Amendment
2052-0399	01/22/1991	Restated Formation Documents
2052-0404	01/22/1991	Registered Agent Change (by Entity)
2102-0151	03/05/1991	Registered Agent Change (by Entity)
2341-0630	12/27/1991	CMS Annual Report Update
2870-1267	07/19/1994	Articles of Amendment
3054-1566	09/19/1995	Assumed Name
3165-1582	04/25/1996	Registered Agent Change (by Entity)
3193-2746	07/16/1996	CMS Annual Report Update
3525-0232	06/19/1998	Assumed Name Cancellation
3525-0233	06/19/1998	Articles of Amendment
3525-0234	06/19/1998	Assumed Name

The attached document(s) was/were filed in this office on the date(s) indicated below:

Reference #	Date Filed	Filing Description	
3660-1140	03/31/1999	Assumed Name	
4624-1714	10/14/2002	2002 Annual Report (Due 10/01/2002)	
5326-2428	01/14/2005	2004 Annual Report (Due 10/01/2004)	
5452-0286	05/06/2005	Registered Agent Change (by Entity)	
5508-0410	07/15/2005	Articles of Amendment	
6525-2160	04/27/2009	Articles of Amendment	
6624-0876	10/19/2009	Articles of Amendment	
A0147-1521	12/18/2012	2012 Annual Report (Due 10/01/2012)	
A0201-1321	09/11/2013	2013 Annual Report (Due 10/01/2013)	

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CHARTER OF JESSE HOLMAN JONES HOSPITAL

The undersigned natural persons having capacity to contract and act as the incorporators of a corporation under the Tennessee General Corporation Ac , adopt the following Charter for such Corporation:

- 1. The name of the corporation is Jesse Holman Jones Hospital.
- 2. The duration of the corporation is perpetual.
- 3. The address of the principal office of the corporation in the State of Tennessee shall be: 509 Brown Street, Springfield, Robertson County, Tennessee.
- 4. The corporation is not for profit.
- 5. The purpose or purposes for which the corporation is organized are:

To provide health care to the general public and to the citizens of Robertson County.

To own and operate hospital and related facilities in Robertson County, Tennessee, and to provide such other hospital and related services as the Board of Trustees shall from time to time determine to be desirable and appropriate.

To do all things which the Board of Trustees determines to be necessary or appropriate in connection or associated therewith.

To operate exclusively for charitable purposes by receiving donations and contributions of real and personal property, holding and managing real property, and distributing said property to Robertson County, Tennessee, or any successor thereto; and to do all other things incidental to or desirable in connection therewith.

- 6. The corporation shall neither have nor exercise any power, nor shall it engage directly or indirectly in any activity, that would invalidate its status (1) as a corporation which is exempt from Federal income taxation as an organization described in Section 501(c)(3) of the Internal Revenue Code of 1986, or (2) as a corporation to which contributions are deductible under Section 170(c)(2) of the Internal Revenue Code of 1986.
- 7. No part of the net earnings of the corporation shall inure to the benefit of or be distributed to its directors, officers, or other private individuals, except that the corporation shall be authorized and empowered to pay reasonable compensation for services rendered

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and to make payments and distributions in furtherance of the B HIP SS set forth in Section 5 hereof.

No substantial part of the activities of the corporation shall consist of attempts to influence legislation by propaganda or otherwise; nor shall it in any manner or to any extent participate in, or intervene in (including the publishing or distributing of statements) any political campaign on behalf of or in opposition to any candidate for public office, nor shall the corporatior engage in any activities that are unlawful under applicable Federal, state, or local laws.

- (a) The business affairs of the corporation shall be controlled by the Board of Trustees (hereinafter the "Board"), which shall be composed of nine (9) members who shall be selected and serve as set forth below. Each member of such Board shall be over the age of twenty-one (21) years, a citizen of Robertson County, Tennessee, and be a resident therein for at least five (5) years prior to the date of his or her selection. It is not necessary that any such members be County Commissioners.
- (b) Except as set forth in subsection (c) below, the initial members of the Board and the expiration date of their initial terms of office shall be as follows:

Name	Term Expires
E. Dee Reid J. W. Dorris, Sr. Hugh Barber, Jr. Howard R. Bradley	8/31/88 8/31/89 8/31/90 8/31/90
Alvin Fowler	8/31/90

- (c) (wo initial members of the Board shall be elected by the Board of County Commissioners of Robertson County, Tennessee (hereinafter the "Commission") and shall serve for initial terms ending August 31, 1988 and August 31, 1989, respectively, as said expiration date shall be designated by the Commission. The other two initial members of the Board shall be active members of the medical staff of Jesse Holman Jones Hospital (hereinafter the "Hospital"), elected by said medical staff and shall serve for initial terms ending August 31, 1988 and August 31, 1989, respectively, as said expiration date shall be designated by the medical staff.
- (d) Upon the expiration of their respective terms, the successor trustees to the two initial members of the Board elected by the Commission and to the office to which Howard R. Bradley is initially named herein shall be persons elected by the Commission. Likewise, upon the expiration of their respective terms, the successor trustees to the two initial members of the Board elected by the medical staff of the Hospital shall be active members of the medical staff elected by the medical staff of the Hospital. All successor

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trustees elected pursuant to this subsection (d) shall be elected G87 DEC 18foMM Der35 of three (3) years from the expiration date of their predecessor's term.

- (e) Upon the expiration of the terms of the members of the Board other than those selected as provided in subsections (d) and (f) of this Section 9, all successor trustees shall be elected by the Board for terms of three (3) years from the expiration date of their predecessor's term.
- (f) In the event any one or more of the members of the Board refuses to serve, resigns or dies while in office, then successor(s) shall be named by the Board at the next regular meeting thereafter and such Trustee or Trustees shall serve out their predecessor's term; provided, however, that a successor named to an office held by a member of the medical staff selected by the medical staff of the Hospital shall be an active member of the medical staff of the Hospital.
- (g) Any Trustee whose term has expired shall continue to serve until his successor shall have been elected in the manner herein provided. Any Trustee shall be eligible for re-election.
- (h) The Board of Trustees shall meet at least quarterly, and more often if necessary; and shall keep complete and permanent records and minutes reflecting all business transactions of the Board.
- 10. (a) The Board of Trustees shall annually cause to be prepared for information purposes a budget reflecting all estimated receipts and disbursements of the corporation.
  - (b) The Board of Trustees shall cause to be prepared for informational purposes annual-audited financial statements within 180 days after the end of each fiscal year of the corporation. Said statements shall be made available to members of the public for their review.
- 11. The corporation is to have no members.
- 12. Upon dissolution of the corporation, the Board of Trustees shall, after paying or making provisions for the payment of all liabilities of the corporation, distribute all assets of the corporation to Robertson County, Tennessee, or any successor thereto.
- 13. The Board of Trustees may take, on written consent without a meeting, any action which they are required or permitted to take by the charter, by-laws, or statutes, provided that such written consent sets forth the action so taken and is signed by all of the directors.

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The corporation shall have all powers provided in the Tennessee not 18 Nother of the Secretary of the extent that the same are not inconsistent with the specific provisions of this Charter.

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DESIGNATION

OF

REGISTERED AGENT

OF

### JESSE HOLMAN JONES HOSPITAL

Pursuant to the provisions of Jection 48-1-120° of the Tennessee General Corporation Act, as amended, the undersigned foreign or domestic corporation or the incorporator or incorporators of a domestic corporation being organized under the Act submit the following statement for the purpose of designating the registered agent for the corporation in the State of Tennessee:

- 1. The name of the corporation is Jesse Holman Jones Hospital.
- The name and street address of its registered agent in the State of Tennessee shall be Norma G. Calhoun, 509 Brown Street, Springfield, Tennessee 37172.

Dated: December 15 , 1987.

JESSE HOLMAN JONES HOSPITAL

Incorporator

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Incorporator

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### ARTICLES OF AMENDMENT TO THE CHARTER

OF

### JESSE HOLMAN JONES HOSPITAL

Pursuant to the provisions of Section 48-60-105 of the Tengosee Nonprofit Corporation Act, the undersigned corporation adopts the following articles of amendment to its charter:

- 1. The name of the corporation is Jesse Holman Junes Hospītal.
- 2. The following is the first charter amendment filed by the Corporation after January 1, 1988. Pursuant to the provisions of Section 48-68-101(b) of the Tennessee Nonprofit Corporation Act, the information required by Section 48-52-102(a) of the Tennessee Nonprofit Corporation Act is included in these Articles of Amendment to the Charter of the Corporation or is otherwise on file in the office of the Secretary of State of Tennessee.
- 3. The Charter is hereby amended by deleting Article 12 in its entirety, and by substituting in lieu thermof, the following new Article 12:
  - 12. Upon dissolution of the corporation, the Board of Trustees shall, after paying or making provisions for the payment of all liabilities of the corporation, distribute all assets of the corporation to Robertson County, Tennessee, or any successor thereto, exclusively for public benefit.
- 4. The Charter is further amended by adding a new Article 15 as follows:
  - 15. The registered office of the corporation is located at 509 Brown Street, Springfield, Robertson County, Tennessee 37172 and its registered agent at that office is Norma C. Calhoun.
- 5. The Charter is further amended by adding a new Article 16 as fellows:
  - 16. The corporation is a public benefit corporation.
- 6. The Charter is further amended by adding a new Article 17 as follows:  $-\frac{1}{\sqrt{6}}$

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- 17. A director of the Corporation shall not be liable GENTRY C to the Corporation or its shareholders for monetary damages SECRETARY for breach of fiduciary duty as a director; provided, however, that this provision does not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the Corporation or its shareholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, or (iii) for a distribution to shareholders that is unlawful. If Tennessee law is amended or modified to authorize corporate action eliminating or further limiting the personal liability of directors, then the liability of a director of the Corporation shall thereupon be eliminated or limited, without the necessity of further amendment of this Charter, to the fullest extent permitted by Tennessee law. Any repeal or modification of the provisions of this Article 17 shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification.
  - Each of the foregoing amendments were duly adopted and approved by written consent of the Board of Trustees of the Corporation on A wember 29, 1988.
  - Additional approval for the amendment was permitted by Section 48-60-301 of the Tennessee Nonprofit Corporation Act was not required.

JESSE HOLMAN JONES HOSPITAL

By: Norma G. Calhoun President

# FIRST AMENDED AND RESTATED CHARTER

OF

# JESSE HOLMAN JONES HOSPITAL

JESSE HOLMAN JONES HOSPITAL (the "Corporation"), a corporation organized and existing under and by virtue of the Tennessee Nonprofit Corporation Act, as amended (the "Act"), does hereby certify as follows:

- 1. That the Corporation's charter as restated below does not contain any amendments that require approval of the members or of any person other than the board of trustees of the Corporation.
- 2. That by written consent executed in accordance with Section 48-58-202 of the Act on December 18, 1990, the board of trustees unanimously approved and adopted the following restated charter, including all amendments contained therein, pursuant to Section 48-60-102(b) and Section 48-60-106 of the Act:
  - 1. The name of the corporation is Jesse Holman Jones Hospital.
    - The duration of the corporation is perpetual.
  - 3. The address of the principal office of the corporation in the State of Tennessee shall be: 509 Brown Street, Springfield, Robertson County, Tennessee 37172.
    - 4. The corporation is not for profit.
  - 5. The purpose or purposes for which the corporation is organized are:

To provide health care to the general public and to the citizens of Robertson County.

To own and operate hospital and related facilities in Robertson County, Tennessee, and to provide such other hospital and related services as the Board of Trustees

shall from time to time determine to be desirable and appropriate.

To do all things which the Board of Trustees determines to be necessary or appropriate in connection or associated therewith.

To operate exclusively for charitable purposes by receiving donations and contributions of real and personal property, holding and managing real property, and distributing said property to Robertson County, Tennessee or any successor thereto; and to do all other things incidental to or desirable in connection therewith.

- 6. The corporation shall neither have nor exercise any power, nor shall it engage directly or indirectly in any activity, that would invalidate its status (1) as a corporation which is exempt from Federal income taxation as an organization described in Section 501(c)(3) of the Internal Revenue Code of 1986, or (2) as a corporation to which contributions are deductible under Section 170(c)(2) of the Internal Revenue Code of 1986.
- 7. No part of the net earnings of the corporation shall inure to the benefit of or be distributed to its directors, officers, or other private individuals, except that the corporation shall be authorized and empowered to pay reasonable compensation for services rendered and to make payment and distributions in furtherance of the purposes set forth in Section 5 hereof.
- 8. No substantial part of the activities of the corporation shall consist of attempts to influence legislation by propaganda or otherwise; nor shall it in any manner or to any extent participate in, or intervene in (including the publishing or distributing of statements) any political campaign on behalf of or in opposition to any candidate for public office, nor shall the corporation engage in any activities that are unlawful under applicable Federal, state, or local laws.
- 9. (a) The business affairs of the corporation shall be controlled by the Board of Trustees (hereinafter the "Board"), which shall be composed of nine (9) members who shall be selected and serve as set forth below. Each member of such Board shall be over the age of twenty-one (21) years, a citizen of Robertson County, Tennessee, and be a resident therein

for at least five (5) Years prior to the date of his or her selection. It is not necessary that any such members be County Commissioners.

(b) Except as set forth in subsection (c) below, the initial members of the Board and the expiration date of their initial terms of office shall be as follows:

<u>Name</u>	Term Expires
E. Dee Reid	8/31/88
J. W. Dorris, Sr.	8/31/89
Hugh Barber, Jr.	8/31/90
Howard R. Bradley	8/31/90
Alvin Fowler	8/31/90

- (c) Two initial members of the Board shall be elected by the Board of County Commissioners of Robertson County, Tennessee (hereinafter the "Commission") and shall serve for initial terms ending August 31, 1988 and August 31, 1989, respectively, as said expiration date shall be designated by the Commission. The other two initial members of the Board shall be active members of the medical staff of Jesse Holman Jones Hospital (hereinafter the "Hospital"), elected by said medical staff, and shall serve for initial terms ending August 31, 1988 and August 31, 1989, respectively, as said expiration date shall be designated by the medical staff.
- (d) Upon the expiration of their respective terms, the successor trustees to the two initial members of the Board elected by the Commission and to the office to which Howard R. Bradley is initially named herein shall be persons elected by the Commission. Likewise, upon the expiration of their respective terms, the successor trustees to the two initial members of the Board elected by the medical staff of the Hospital shall be active members of the medical staff elected by the medical staff of the Hospital. All successor trustees elected pursuant to this subsection (d) shall be elected for terms of three (3) years from the expiration date of their predecessor's term.
- (e) Upon the expiration of the terms of the members of the Board other than those selected as provided in subsections (d) and (f) of this Section 9, all successor trustees shall be elected by the Board for terms of three (3) years from the expiration date of their predecess its term.

- (f) In the event any one or more of the members of the Board refuses to serve, resigns or dies while in office, then successor(s) shall be named by the Board at the next regular meeting thereafter and such Trustee or Trustees shall serve out their predecessor's term; provided, however, that a successor named to an office held by a member of the medical staff selected by the medical staff of the Hospital shall be an active member of the medical staff of the Hospital.
- (g) Any Trustee whose term has expired shall continue to serve until his successor shall have been elected in the manner herein provided. Any Trustee shall be eligible for re-election.
- (h) All successor Trustees named or elected to the Board of Trustees shall be submitted to the Board of County Commissioners of Robertson County, Tennessee for their approval. Absent such approval, the incumbent Trustee shall remain in office.
- (i) The Board of Trustees shall meet at least quarterly, and more often if necessary; and shall keep complete and permanent records and minutes reflecting all business transactions of the Board.
- 10. (a) The Board of Trustees shall annually cause to be prepared for information purposes a budget reflecting all estimated receipts and disbursements of the corporation.
- (b) The Board of Trustees shall cause to be prepared for informational purposes annual-audited financial statements within 180 days after the end of each fiscal year of the corporation. Said statements shall be made available to members of the public for their review.
  - 11. The corporation is to have no members.
- 12. Upon dissolution of the corporation, the Board of Trustees shall, after paying or making provisions for the payment of all liabilities of the corporation, distribute all assets of the corporation to Robertson County, Tennessee, or any successor thereto, exclusively for public benefit.
- 13. The Board may take, on written consent without a meeting, any action which they are required or permitted to take by the charter, by-laws, or statutes, provided that such written consent sets forth

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the action so taken and is signed by all of the members of the Board.

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- 14. The corporation shall have all powers provided in the Tennessee Nonprofit Corporation Act, as now or hereafter in effect, to the extent that the same are not inconsistent with the specific provisions of this Charter.
- 15. The registered office of the corporation is located at 509 Brown Street, Springfield, Robertson County, Tennessee 37172 and its registered agent at that office is Edward D. Luke.
- 16. The corporation is a public benefit corporation.
- 17. A trustee of the corporation shall not be liable to the corporation for monetary damages for breach of fiduciary duty as a trustee; provided, however, that this provision does not eliminate or limit the liability of a trustee (i) for any breach of the trustee's duty of loyalty to the corporation, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, or (iii) for a distribution that is unlawful. If Tennessee law is amended or modified to authorize corporate action eliminating or further limiting the personal liability of directors or trustees, then the liability of a trustee of the corporation shall thereupon be eliminated or limited, without the necessity of further amendment of this Charter, to the fullest extent permitted by Tennessee law. Any repeal or modification of the provisions of this Article 17 shall not adversely affect any right or protection of a trustee of the corporation existing at the time of such repeal or modification.

JESSE HOLMAN JONES HOSPITAL

Edward D. Luke, President

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# DESIGNATION OF REGISTERED AGENT

OF

# JESSE HOLMAN JONES HOSPITAL

Pursuant to the provisions of Section 48-55-102 of the Tennessee Nonprofit Corporation Act, as amended, the undersigned corporation hereby submits this application:

- 1. The name of the corporation is Jesse Holman Jones Hospital.
- 2. The street address of its current registered office is 509 Brown Street, Springfield, Robertson County, Tennessee 37172.
- The name of its current registered agent is Norma G. Calhoun.
  - 4. The name of its new registered agent is Edward D. Luke.
- 5. The street addresses of the registered office and the business office of the registered agent are identical.

Dated: December /8, 1990.

JESSE HOLMAN JONES HOSPITAL

Edward D. Luke, President

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# DESIGNATION OF REGISTERED AGENT

OF

### JESSE HOLMAN JONES HOSPITAL

Pursuant to the provisions of Section 48-55-102 of the Tennessee Nonprofit Corporation Act, as amended, the undersigned corporation hereby submits this application:

- 1. The name of the corporation is Jesse Holman Jones Hospital.
- 2. The street address of its current registered office is 509 Brown Street, Springfield, Robertson County, Tennessee 37172.
- 3. The name of its current registered agent is Edward D. Luke.
  - The name of its new registered agent is John M. Faulkner.
- 5. The street addresses of the registered office and the business office of the registered agent are identical.

Dated: February // 1991.

JESSE HOLMAN JONES HOSPITAL

John M. Faulkner, President

CORPORATION ANNUAL REPORT STATE OF TENNESSEE SECRETARY OF STATE RRAT, DESC. · 14年的最初的 15月1年 FEMQ FEE -610.07 CURRENT FISCAL YEAR CLOSING MONTH IF DEFERENT. CORRECT MONTHS 06/30 04/01/92 THIS REPORT IS DUE ON OR BEFORE 62-1046595 (1) SECRETARY OF STATE CONTROL NUMBER: OR FEDERAL EMPLOYER IDENTIFICATION NUMBER: 0198302 (28.) STATE OR COUNTRY OF INCORPORATION: (2A.) NAME AND MALING ADDRESS OF CORPORATION JESSE HOLMAN JONES HUSPITAL **TENNESSEE** 509 BROWN STREET (2C.) ADD OR CHANGE MALING ADDRESS: SPRINGFIELD, TN 37172 Zip + 4 ... 37172-2984 12/18/1987 NON-PROFIT A PHINCIPAL ADDRESS INCLUDING CITY, STATE, ZIP CODE: 509 BROWN STREET, SPRINGFIELD, TN 37172 B. CHANGE OF PRINCIPAL ADDRESS: ZIP CODE + 4 STREET CITY STATE 37172 2984 \*\* BLOCKS 4A AND 4B MUST BE COMPLETED OR THE ANNUAL REPORT WILL BE RETURNED \*\* (4) Z. NAME AND BUSINESS ADDRESS INCLUDING ZIP CODE, OF THE PRESIDENT, SECRETARY AND OTHER PRINCIPAL OFFICERS (ATTACH ADDITIONAL SHEET IF N° CESSARY.) CITY STATE 24 COME -THE **GUSPIESS ADDRESS** Springfield, 当N 37772-2984 John M. Faulkner EXESIDENT 509 Brown Street Phyllis Pulley 509 Brown Street Springfield, TN 37172-2984 SPERSTARY Springfield, TN 37172-2984 Treasurer Edward D. Luke 509 Brown Street B. BOARD OF DIRECTORS (NAMES, BUSINESS ADDRESS MICLUE'NG ZIP CODE) (ATTACH ADDITIONAL SHEET IF NECESSARY.) SAINE AS ADOVE I HONE OR LIST BLLOW BUSINESA ADDRESS See Attached List (E) A NAME OF REGISTERED AGENT AS APPEARS ON SECRETARY OF STATE RECORDS: JOHN M. FAULKYER BI REGISTERED ADDRESS AS APPEARS ON SECRETARY OF STATE RECORDS: 509 BROHN STREET, SPRINGFIELD, IN 37172 (6) INDICATE BELOW ANY CHANGES TO THE REDISTERED AGENT NAME AND/OR REGISTERED OFFICE (BLOCK 54 AND/OR 58) THERE IS AN ADDITIONAL \$10.00 FILING FEE FOR CHINGES MADE TO THIS INFORMATION A. CHANGE OF REGISTERED AGENT: D. CHANGE OF REGISTERED OFFICE: ZIF CODE + 4 COMPORATIONS, OUR RECORDS REFLECT THAT YOUR NONPROFIT COMPORATION IS A PUBLIC BENEFIT OR A MUTUAL (7) THIS BOX APPLIES ONLY TO NONE. CORE
BENEFIT CORPORATION: AS INDICATED DELOW IF BLANK OR CHANGE, PLEASE CHECK APPROPRIATE BOX: PUBLIC PUBLIC MUTUAL

(8) SIGNATURE PHYSICS THERMS INCIDENT TO PLEASE CHECK BOX UNLESS OTHERWISE INCIDENT TO PRELIGIOUS

(8) SIGNATURE PHYSICS TURBY

(9) DATE December 18, 1991

(10) TYPE/PRINT NAME OF GUNER PHYSILS PURISE

(11) TITLE OF SIGNER Corporate Secretary

# JESSE HOLMAN JONES, HOSPITAL

# BOARD OF TRUSTEES

Hugh Barber - Chairman P.O. Box 666 Springfield, TN 37172 Occupation: Barber Motor Co. 384-4499 (W) 384-2957 (H) 384-9413 (Randolph's Gifts) BOARD MEMBER SINCE: 1975

James G. Bowens
209 20th Avenue West
Springfield, TN 37172
Occupation: Utility Person for
Delight Products
384-3189 (H) 384-9924 (W)
BOARD MEMBER SINCE: 1988

Howard R. Bradley 521 South Pawnee Drive Springfield, TN 37172 Occupation: School Teacher 384-3516 (W) 384-6952 (H) 384-4220 (H) BOARD MEMBER SINCE: 1983

T.H. Crunk, M.D.
hllside Clinic
900 Brown Street
Springfield, TN 37172
Occupation: Family Practitioner
384-2482 (W)
BOARD MEMBER SINCE: 1988

Alvin Fowler 6028 Gunn Road Springfield, TN 37172 Occupation: Owner-Springfield Auto Parts 384-7571 (W) 384-9089 (H) BOARD MEMBER SINCE: 1971

T.C. Krueger, M.D.
Medical Arts Building
205 Fifth Avenue Bast
Springfield, TN 37172
Occupation: Surgeon
384-4060 (W) 384-9628 (H)
BOARD MEMBER SINCE: 1991

E. Dee Reid P.O. Box 424 White House, TN 37188 Occupation: Real Estate 672-0333 (W) 672-3226 (H) FAX 672-0351 BOARD MEMBER SINCE: 1975

Steve Sanders.
Highway 41 South
Springfield, TN 37172
Occupation: Owner-Sanders Honda
643-7859 (W) 643-0447 (H)
FAX 643-0951
BOARD MEMBER SINCE: 1988

Ted Stubblefield
111 Fifth Avenue West (316 Oak St.)
Springfield, TN 37172
Occupation: Nationwide Insurance
384-0607 (W) 384-5961 (H)
FAX 384-1260
BOARD MEMBER SINCE: 1989

REV. 5/10/91 ADMINISTRATION Sty JII 19 M 4: 09

SIGNET DARNET FIRST AMENDED AND RESTATED CHARTER

OF

CARTERS OF STREET

### JESSE HOLMAN JONES HOSPITAL

Pursuant to the provisions of Section 48-60-105 of the Tennessee Nonprofit Corporation Act, as amended (the "Act"), the undersigned, Jesse Holman Jones Lospital, a Tennessee nonprofit corporation (the "Corporation"), adopts the following articles of amendment to its First Amended and Restated Charter:

- 1. The name of the Corporation is Jesse Holman Jones Hospital.
- 2. The Charter is hereby amended by adding to the end of Article 9 the following new subsection (j).
  - (j) During the term of the Reimbursement and Credit Agreement, the Affiliation Agreement, and the Revolving Credit Agreement between the Corporation and Columbia/HCA Healthcare Corporation (collectively, the "Credit Agreements"), Columbia/HCA Healthcare Corporation shall appoint two non-voting members to the Board to serve for such term or terms as Columbia/HCA Healthcare Corporation shall determine; provided, however, that the term of any such non-voting member shall not extend beyond the term of the Credit Agreements. Any non-voting members appointed hereunder shall serve in addition to the members described in subsection (a) above.
- 3. The date of adoption of the foregoing amendment to the First Amended and Restated Charter of the Corporation is July 19, 1994.
- 4. Pursuant to Section 48-60-102(b) of the Act, the foregoing amendment was duly adopted and approved by vote of the trustees of the Corporation at a meeting held on July 19, 1994, there being no members of the Corporation.

# Hugero d.Jes

Section 48-60-301 of the Act, is not required.

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Dated July 19 1994

SECRE ARY OF SUESSE HOLMAN JONES HOSPITAL

कामाध्य ना प्रदेशक

# APPLICATION FOR REGISTRATION OF ASSUMED CORPORATE NAME

95 SEP 19 AM 8: 56

Pursuant to the provisions of Section 48-14-101(d) of the Tennessee Business Corporation Act or Section 48-54-101(d) of the Tennessee Nonprofit Corporation Act, the undersigned corporation hereby submits this application:

1. The true name of the corporation is =	JESSE HOLMAN JONES HOSPITAL
2. The state or country of incorporation	sTENNESSEE
The corporation intends to transact bu     XKKMXAMMNMXKKMX从HHK	siness in Tennessee under an assumed corporate name.
The corporation is nonprofit.	
[NOTE: Please strike the sentence which does	not apply to this corporation.]
5. The assumed corporate name the corpo	pration proposes to use is <u>NORTHCREST MEDICAL CENTER</u>
[NOTE: The assumed corporate name must m Corporation Act or Section 48-54-101 of the l	eet the requirements of Section 48-14-101 of the Tennessee Business Fennessee Nonprofit Corporation Act.]
August 29, 1995	JESSE HOLMAN JONES HOSPITAL
Signature Date	Name of Corporation
President & CEO	Skum Taulkall
Signer's Capacity	Signature
	John M. Faulkner
	Name (typed or printed)

P.

# CHANGE OF REGISTERED OFFICE AND REGISTERED AGENT

Pursuant to the provisions of Section 48-55-102 of the Tennessee Nonprofit Corporation Act, as amended, the undersigned hereby submits this application:

- The name of the corporation is Jesse Holman Jones Hospital L
- The street address of its current registered office is 509 Brown Street, Springfield, Robertson County, Tennessee 37172.
- The street address of the new registered office is 100 NorthCrest Drive, Springfield, Robertson County, Tennessee 37172.
  - The name of the current registered agent is John M. Faulkner. 4.
- The name of the new registered agent is Dennis T. Bynum. The street address of his office is 100 NorthCrest Drive, Springfield, Robertson County, Tennessee 37172.
- After the changes, the street address of the registered office and the business office of the registered agent will be identical

April 19 , 1996

JESSE HOLMAN JONES HOSPITAL d/b/A NorthCrest Medical Center

	3: 1 13.3	2000年6日
CORPORATION ANNUAL REPORT STATE OF TENNESSEE SECRETARY OF STATE SUITE 1800, JAMES K. POLK BUILDING NASHVILLE, TN 37243-0308 AMOUNT DUE - \$20.00		
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(1) SECRETARY OF STATE CONTROL NUMBER: 0198302	OR FEDERAL EMPLOYER	R IDENTIFICATION NUMBER:
(2A.) NAME AND MAILING ADDRESS OF CORPORATION:	(29	) STATE OF COUNTRY OF INCORPORATION:
JESSE HOLMAN JONES HOSPITAL 509 BROWN STREET		TENNESSEE
SPRINGFIELD, IN 37172-2984	120	C) ADD OR CHANGE MAILING ADDRESS
		NorthCrest Medical Center 100 NorthCrest Drive Springfield, IN 37172-3961
D 12/18/1987 NON-PROFIT		
(3) A PRINCIPAL ADDRESS INCLUDING CITY, STATE OF CODE: 509 BROWN STREET, SPRINGFIELD.	TN 37172-2	984
B. CHANGE OF PRINCIPAL ADDRESS:		ute.
STREET	CITY	STATE ZIP CODE +4
100 NorthCrest Drive	Springfield	IN 371.72-3961
* * BLOCKS 4A AND 4B MUST BE COMPLET	ED OR THE AN	NUAL REPORT WILL BE RETURNED * *
(4) A. NAME AND BUSINESS ADDRESS, INCLUDING DIP CODE, OF THE PRESK (ATTACH ADDITIONAL SHEET IF NECEBBARY.)	DENT, SECRETARY AND	OTHER PRINCIPAL OFFICERS
TILE	BUSINESS ADORE	SS CITY, STATE ZP CODE . 4
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SECRETARY Phyllis T. Pulley	100 NorthCr	est Drive Springfield, TM 37172-3961
SECRETARY Phyllis T. Pulley	100 NorthCr	est Drive Springfield, IN 37172-3961
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# NORTHCREST MEDICAL CENTER BOARD OF TRUSTEES

246.

David Bellar 701 16th Avenue East Springfield, TN 37172

James G. Bowens 209 20th Avenue West Springfield, TN 37172

Howard R. Bradley
521 South Pawnee Drive
Springfield, TN 37172

T.H. Crunk, M.D. NorthCrest Physicians Plaza 224 NorthCrest Drive Springfield, TN 37172

Alvin Fowler 6028 Gunn Road Springfield, TN 37172

J.T. Gray, M.D.
NorthCrest Medical Center
Medical Imaging Department
100 NorthCrest Drive
Springfield, TN 37172

E. Dee Reid - Chairman P.O. Box 424 White House, TN 37188

Steve Sanders 3314 Highway 41 South Springfield, TN 37172

Ted Stubblefield 111 Fifth Avenue West Springfield, TN 37172 2 12

# APPLICATION FOR CANCELLATION OF ASSUMED CORPORATE NAME

Pu-suant to the provisions of Section 48-14-101(e) of the Tennessee Business Corporation Act or Section 48-54-101(e)

# ARTICLES OF AMENDMENT

# TO THE FIRST AMENDED

# AND RESTATED CHARTER OF

# JESSE HOLMAN JONES HOSPITAL

Pursuant to the provisions of Section 48-60-105 of the Tennessee Nonprofit Corporation Act, as amended (the "Act"), the undersigned, Jesse Holman Jones Hospital, a Tennessee nonprofit corporation (the "Corporation"), adopts the following articles of amendment to its First Amended and Restated Charter (the "Charter"):

- 1. The name of the corporation is Jesse Holman Jones Hospital.
- 2. The Charter is hereby amended by changing the name of the Corporation to NorthCrest Medical Center.
- 3. The date of adoption of the foregoing amendment to the First Amended and Restated Charter of the Corporation is <u>June 16</u>, 1998.
- 4. Pursuant to Section 48-60-102(b) of the Act, the foregoing amendment was duly adopted and approved by vote of the trustees of the Corporation on <u>June 16</u>, 1998, there being no members of the Corporation.
- 5. Additional approval of this amendment, as permitted by Section 48-60-301 of the Act, is not required.

Dated June 16 , 1998.

NORTHCREST MEDICAL CENTER

Rv

Title:

President/CEO

# APPLICATION FOR REGISTRATION OF ASSUMED CORPORATE NAME

Pursuant to the provisions of Section 48-14-101(d) of the Tennessee Business Corporation Act or Section 48-54-101(d) of the Tennessee Nonprofit Corporation Act, the undersigned corporation hereby submits this application:

1. The true name of the corporation is	NORTHCREST, MEDICAL CENTER
2. The state or country of incorporation is	TENNESSEE
3. The corporation intends to transact business	in Tennessee under an assumed corporate name.
4. The assumed corporate name the corporation	n proposes to use is
JESSE HOLMA	N JONES HOSPITAL
[NOTE: The assumed corporate name must me Corporation Act or Section 48-54-101 of the Tourist of	NORTHCREST MEDICAL CENTER Name of Corporation  William A. Kenley
	Name (typed or printed)

# APPLICATION FOR REGISTRATION OF ASSUMED CORPORATE NAME

Tief.

Pursuant to the provisions of Section 48-14-101(d) of the Tennessee Business Corporation Act or Section 48-54-101(d) of the Tennessee Nonprofit Corporation Act, the undersigned corporation hereby submits this application:

1. The true name of the corporation is Nort	hCrest Medical Center	- 10 ×
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2. The state or country of incorporation is		
3. The corporation intends to transact business in	n Tennessee under an assumed corporate name.	
4. The assumed corporate name the corporation NorthCrest Fou		
[NOTE: The assumed corporate name must mee Corporation Act or Section 48-54-101 of the Ter	et the requirements of Section 48-14-101 of the Tennessee Bu	usiness
3/S(JOE) Signature Date	NorthCrest Medical Center Name of Corporation	many (44) and
President Signer's Capacity	Signature	×
	William Kenley Name (typed or printed)	a

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1. 18. 19. 19. 19. 19. 19. 19. 19. 19. 19. 19		
	OM ANNUAL REPORT	Please return completed form to: TEHHESSEE SECRETARY OF STATE Attn: Annual Report 312 Eighth Ave. N, 6th Floor William R. Snodgrass Tower Nashville, TN. 37243
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ITI SECRETARY OF STATE CONTROL NUMBER 0198302	1	
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20KINGELETT - TH 32755-38P?		
D 12/18/1987 NON-PROFIT		
A PRINCIPAL ADDRESS INCLUDING CITY STATE ZIP CODE 100 NORTHCREST DRIVE SPRINGFIELD TN 37172-3961		
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(II) CHANGE OF REGISTERED OFFICE: D. LANGETY CITY	DEME STUTTED TI	J 31172-3761 Kent.
PUBLIC	INCORRECT, PLEASE CHECK AP	PROPRIATE BOX: PUBLIC BENEFIT OR A PUBLIC MUTUAL.
B IF A TENNESSEE RELIGIOUS CORPORATION PLEASE CHECK BOX IF BLANK		
(8) SIGNATURE	(9) DATE	+ 01,02
101 TYPE PRINT NAME & SIGNER William Kinley	III) TITLE OF	SIGNER President/CEU
. THIS REPORT MUST	T BE DATED AND SIGNED	• •

The Cartes and Annual Control of the Control of the

NorthCrest Medical Center Board of Trustees

David Bellar 152 Eagle Pointe Springfield, TN 37172

James G. Bowens P.O. Box 1135 Springfield, TN 37172

Howard R. Bradley – Vice Chairman 101 Qualls Court Springfield, TN 37172

Paul Douthitt, M.D. 426 22<sup>nd</sup> Avenue East Springfield, TN 37172

Alvin Fowler - Secretary 6028 Gunn Road Springfield, TN 37172

Paul D. Hartzheim, M.D. 101 E. Mooreland Springfield, TN 37172

E. Dee Reid – Chairman P.O. Box 424 White House, TN 37188

Steve Sanders 3314 Highway 41 South Springfield, TN 37172

Ted H. Stubblefield 111 Fifth Avenue West Springfield, TN 37172

Sabi Kumar, M.D. - Chief of Staff 100 NorthCrest Drive Springfield, TN 37172

Annual Report Filing Fee Due: \$20, if no changes are made in block #6 to the registered agent/of \$40, if any changes are made in block #6 to the registered agent/o	ice, or	≥ 14 × 20 ≥ Attn 312 Willi	se return complete NESSEE SECRETAI : Annual Report Eighth Ave N, 6th F am R. Snodgrass To hville, TN, 37243	RY OF STATE
CURRENT FISCAL YEAR CLOSING MONTH. 06 IF DIFFERENT, CORRECT MONTH IS	THIS REPORT IS DU	IE ON OR BEFORE	10/01/04	
(1) SECRETARY OF STATE CONTROL NUMBER: 0198302				
(2A.) NAME AND MAILING ADDRESS OF CORPORATION:	(3	B.) STATE OR COUNTRY	OF INCORPORATION:	
NORTHCREST MEDICAL CENTER		TENNESSI	32	
100 NORTHCREST DRIVE SPRINGFIELD, TN 37172-3961	(2	C.) ADD OR CHANGE M	AILING ADDRESS:	
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(4) NAME AND BUSINESS ADDRESS, INCLUDING ZIP CODE, OF THE PRESIDER (ATTACH ADDITIONAL SHEET IF NECESSARY.)	VT, SECRETARY AND OTHER	R PRINCIPAL OFFICERS.		
IITLE NAME	DUSINESS /	ADDRESS	CITY, STATE, 21	CODE + 4
PRESIDENT GEORGE ASSELL	100 North	rest Drive	Springfield, 1	1437172
PRESIDENT GEORGE ASSETT	100 North	Crest Drive	Springfield	, TN 37174
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(5) BOARD OF DIRECTORS (NAMES, BUSINESS ADDRESS INCLUDING ZIP COLOR USTED BELOW: NAME	DE). (ATTACH ADDITIONAL: BUSINESB ADDRES	SHEET IF NECESSARY.) 8	SAME AS ABOVE CITY, STATE, Z	IP COBE + 4
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C. INDICATE BELOW ANY CHANGES TO THE REGISTERED AGENT NAME AN	D/OR REGISTERED OFFICE.		9 1 2	31 7 8
(). CHANGE OF REGISTERED AGENT: GOOGE AS	hall			
(I). CHANGE OF REGISTERED AGENT: 1709 C. 715	KILLI	A.	3/-	- California
IN. CHANGE OF REGISTERED OFFICE: STREET CITY	STATE TH		ZIP CODE 1 4	COUNTY
	RDS REFLECT THAT YOUR IR INCORRECT, PLEAS			OR A PUBLIC MUTUAL
PUBLIC  B. IF A TENNESSEE RELIGIOUS CORPORATION, PLEASE CHECK BOX IF BLA	NK.	☐ RELIG	IOUS	
(6) SIGNATURE		(9) DATE / -10 - C		
AND THE PRINT HAVE OF SIGNED				******
(10) TYPE PRINT NAME OF SIGNER:		President	1CEO	



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# NORTHCREST MEDICAL CENTER BOARD OF TRUSTEES

David Bellar 152 Eagle Pointe Springfield, TN 37172

James G. Bowens P.O. Box 1135 Springfield, TN 37172

Howard Bradley 101 Qualls Court Springfield, TN 37172

Sabi S. Kumar, M.D. 322 NorthCrest Drive Springfield, TN 37172

Neil Dressler, M.D. 502-C South Main Street Springfield, TN 37172

Alvin Fowler 6028 Gunn Road Springfield, TN 37172

E. Dee Reid - Chairman P.O. Box 424 White House, TN 37188

Steve Sanders 3314 Highway 41 South Springfield, TN 37172

Ted H. Stubblefield 111 Fifth Avenue West Springfield, TN 37172 STATE AN IL AN IL: 37



# Bepartment of State

Corporate Filings
312 Eighth Avenue North
6th Floor, William R. Snodgrass Tower
Nashville, TN 37243

SS-4427 (Rev. 6/03)

For Office Use Only

CHANGE OF REGISTERED AGENT/OFFICE
(BY CORPORATION)::

PATE

**RDA 1678** 

Pursuant to the provisions of Section 48-13-102 or 48-25-108 of the Tennessee Business Corporation Act or Section 48-55-102 or 48-65-108 of the Tenner → Nonprofit Corporation Act, the undersigned corporation hereby submits this application: 1. The name of the corporation is NorthCrest Medical Center 2. The street address of its current registered office is \_\_\_\_\_100 Northcrest Drive, Springfield, TN 37172-3961 3. If the current registered office is to be changed, the street address of the new registered office, the zip code of such office, and the county in which the office is located is\_\_\_ George Asbell 4. The name of the current registered agent is \_\_\_ 5. If the current registered agent is to be changed, the name of the new registered agent is Scott Raynes 6. After the change(s), the street addresses of the registered office and the business office of the registered agent will be identical. NorthCrest Medical Center Name of Corporation President and CEO Signature Signer's Capacity Scott Raynes Name (typed or printed)

Filing Fee \$20.00

蛋异口毒 印度九百

# ARTICLES OF AMENDMENT TO TO THE FIRST AMENDED AND RESTATED CHARTER OF NORTHCREST MEDICAL CENTER 1 37 07 STATE

Pursuant to Section 48-60-105 of the Tennessee Nonprofit Corporation Act, as amended (the "Act"), the underlined, Northerest Medical Center, a corporation (the "Corporation"), adopts the following articles of amendment to its First Amended and Restated Charter:

- 1. The name of the Corporation is: Northerest Medicai Center.
- 2. The First Amended and Restated Charter of the Corporation is hereby amended by deleting the first sentence of subparagraph (a) of Article 9 in its entirety and inserting in its place the following sentence:
  - "(a) The business affairs of the corporation shall be controlled by the Board of Trustees (hereinafter the "Board"), which shall be comprised of cleven (11) voting members who shall be selected and serve as set forth below."
- 3. The First Amended and Restated Charter is hereby further amended by adding a new subparagraph (k) to Article 9 which shall read as follows:
  - "(k) Two additional voting members of the Board shall be selected as follows. The Board shall elect one additional member whose name shall be submitted to the Board of Commissioners of Robertson County for their approval. The second additional Board member shall be nominated by the Board and his or her name submitted to the Board of Commissioners of Robertson County who shall elect the person who is to become this additional member of the Board. These two additional voting members shall serve an initial term commencing upon their approval or election, respectively, by the Board of Commissioners of Robertson County and expiring on August 31, 2007 and August 31, 2008, respectively, and their successors shall be chosen in like manner for terms of three (3) years from the expiration date of their predecessor's term."
- 4. The date of adoption of the foregoing amendment to the First Amended and Restated Charter of the Corporation is June 21, 2005.

# 'अव्यामक सम्बद्ध

- Pursuant to Section 48-60-102(b) of the Act, the foregoing amendment
  was duly adopted and approved by the vote of the Trustees of the Corporation at a
  meeting held on June 21, 2005, there being no members of the Corporation.
- Additional approval of the amendment, as permitted by Section 48-60-301
   of the Act, is not required.

Dated: June 21, 2005

**NORTHCREST MEDICAL CENTER** 

202345 L/\$15.5

## ARTICLES OF AMENDMENT TO THE FIRST AMENDED AND RESTATED CHARTER 700 APR 27 PH 2: 57

OF
NORTHCREST MEDICAL CENTER

SECRETA

Pursuant to Section 48-60-105 of the Tennessee Nonprofit Corporation Act, as amended (the "Act"), the undersigned, Northcrest Medical Center, a Tennessee nonprofit corporation (the "Corporation"), adopts the following articles of amendment to its First Amended and Restated Charter:

- 1. The name of the Corporation is: Northcrest Medical Center.
- 2. The First Amended and Restated Charter of the Corporation is hereby amended by deleting the first sentence of subsection (a) of Article 9 in its entirety and inserting in its place the following sentence:
  - "(a) The business affairs of the corporation shall be controlled by the Board of Trustees (hereinafter the "Board"), which shall be comprised of twelve (12) voting members who shall be selected and serve as set forth below."
- 3. The First Amended and Restated Charter is hereby further amended by deleting subsection (e) of Article 9 and substituting therefore the following as the new language of subsection (e) which shall read as follows:
  - "(e) Upon the expiration of the terms of the members of the Board other than those selected as provided in subsections (d), (f) and (j) of this Section 9, all successor trustees shall be elected by the Board for terms of three (3) years from the expiration date of their predecessor's term.
- 4. The First Amended and Restated Charter is hereby further amended by deleting subsection (j) and subsection (k) of Article 9 and substituting therefore the following as the new language of subsection (j) which shall read as follows:
  - "(j) Three additional voting members of the Board shall be selected as follows. The Board shall elect two additional members whose names shall be submitted to the Board of Commissioners of Robertson County for their approval. The initial term of one of these members (which was originally added to the Board by a 2005 Amendment) expired on August 31, 2007 and the one added by this amendment shall have an initial term ending August 31, 2009. The third additional Board member (which was originally added to the Board by a 2005 Amendment) shall be nominated by the Board

and his or her name submitted to the Board of Commissioners of TENNESSEE Robertson County who shall elect the person who is to become this additional member of the Board. This member's initial term APR 27 PH 2: 57 expired on August 31, 2008. Their successors shall be chosen in like manner for terms of three (3) years from the expiration date of STATE their predecessor's term."

- 3. The date of adoption of the foregoing amendment to the First Amended and Restated Charter of the Corporation is  $\frac{4/21/69}{}$ .
- 4. Pursuant to Section 48-60-102(b) of the Act, the foregoing amendment was duly adopted and approved by the Board of Trustees of the Corporation, there being no members of the Corporation.
- 5. Additional approval of the amendment, as permitted by Section 48-60-301 of the Act, is not required.

Dated: 4/21/09

NORTHCREST MEDICAL CENTER

By: SWAK ayne Title: Pheoident &

879579.01/600515-000005

RECEIVED STATE OF TENNESSEE

# TO 2009 OCT 19 PM 3: 04 THE FIRST AMENDED AND RESTATED CHARTER OF THE FIRST AMENDED AND RESTATED CHARTER NORTHCREST MEDICAL CENSECTERY OF STATE

Pursuant to Section 48-60-105 of the Tennessee Nonprofit Corporation Act, as amended (the "Act"), the undersigned, Northcrest Medical Center, a Tennessee nonprofit corporation (the "Corporation"), adopts the following articles of amendment to its First Amended and Restated Charter:

- 1. The name of the Corporation is: Northcrest Medical Center.
- 2. The First Amended and Restated Charter of the Corporation is hereby amended by deleting the second sentence of subsection (a) of Article 9 in its entirety and inserting in its place the following sentence:
  - "(a) ...Except for the two members of the medical staff elected by the medical staff of the Hospital and up to two additional members of the Board of Trustees, each member of such Board shall be over the age of twenty-one (21) years, a citizen of Robertson County, Tennessee, and be a resident therein for at least five (5) years prior to the date of his or her selection."
- 3. The date of adoption of the foregoing amendment to the First Amended and Restated Charter of the Corporation is 9/15/09.
- 4. Pursuant to Section 48-60-102(b) of the Act, the foregoing amendment was duly adopted and approved by the Board of Trustees of the Corporation, there being no members of the Corporation.
- 5. Additional approval of the amendment, as permitted by Section 48-60-301 of the Act, is not required.

Dated: 10/15/09

NORTHCREST MEDICAL CENTER

Title:

975811.01/600515-000005



## Tennessee Corporation Annual Report Form

AR Filing #: 03247071 FILED: Dec 18, 2012 9:36AM

File online at: http://TNBear.TN.gov/AR

Due on/Before: 10/01/2012

Reporting Year: 2012

Annual Report Filing Fee Due:

\$20 if no changes are made in block 3 to the registered agent/office, or \$40 if any changes are made in block 3 to the registered agent/office

This Annual Report has been successfully paid for and filed. Please keep this report for your records.

CC Payment Ref #: 148130172

SOS Control Nun Corporation Non-F		Date Forme	ed: 12/18/1987	Formation Locale: TENNESSEE		
(1) Name and Ma NORTHCREST MI ACCOUNTING DE 100 NORTHCRES SPRINGFIELD, TR	EDICAL CENTER EPT BT DR		100 NORTH	.D, TN 37172-3961	lma	
SCOTT RAYNES 100 NORTHCRES SPRINGFIELD, TI	N 37172-3961		Age	nt County: ROBERTSON COUNTY	Image #: A014/-1521	
Title	Name		t, Secretary and other p		_	
SECRETARY	JAMES F SCHI		100 NORTHCREST DR	City, State, Zip SPRINGFIELD, TN 37172	_	
PRESIDENT	SCOTT B RAYN		100 NORTHCREST DR			
	rs names and busines					
Name		Business Addres		City, State, Zip		
TED STUBBLEFIELI	J	100 NORTHCREST	DR	SPRINGFIELD, TN 37172	SPRINGFIELD, TN 37172	
A. Our records If blank or ir B. If a Tenness	ncorrect, please chec see religious corpora	n-profit corporation ck appropriately:		a mutual benefit corporation as indicated.		
(7) Signature: Electronic			(8) Dat	e: 12/18/2012 9:36 AM		
(9) Type/Print Name: Kim Pridgen						



## Tennessee Corporation Annual Report Form

File online at: http://TNBear.TN.gov/AR

Due on/Before: 10/01/2013

Reporting Year: 2013

AR Filing #: 03769445 FILED: Sep 11, 2013 1:30PM DLN #: A0201-1321.001

Annual Report	Filing	Fee	Due:
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\$20 if no changes are made in block 3 to the registered agent/office, or \$40 if any changes are made in block 3 to the registered agent/office

This Annual Report has been successfully paid for and filed. Please keep this report for your records.

CC Payment Ref #: 152102915

SOS Control Number Corporation Non-Profi		Date Forme	ed: 12/18/1987	Formation Lo	cale: TENNESSEE	
(1) Name and Mailin NORTHCREST MEDI ACCOUNTING DEPT 100 NORTHCREST I SPRINGFIELD, TN 3	CAL CENTER DR		ACCOUNT 100 NORT	oal Office Address: TNG DEPT HCREST DR ELD, TN 37172-39	61	
(3) Registered Agent RANDALL DAVIS 100 NORTHCREST I SPRINGFIELD, TN 3	DR .	ered Office (RO)		gent Changed: <u>Yes</u> gent County: ROB	BERTSON COUNTY	
(4) Name and business	address (with zip co	de) of the Presiden	it, Secretary and othe	er principal officers.		
Title	Name		Business Address		City, State, Zip	
PRESIDENT	RANDALL DAVIS	3	100 NORTHCREST	DR	SPRINGFIELD, TN 37172-3961	
SECRETARY	JAMES F SCHMI	TO	100 NORTHCREST	DR	SPRINGFIELD, TN 37172	
(5) Board of Directors n	ames and business	address (with zip co	ode) None, or li	sted below.		
Name	I	Business Addres	SS	City, St	ate, Zip	
TED STUBBLEFIELD		100 NORTHCREST	NORTHCREST DR		SPRINGFIELD, TN 37172	
	lect that your non- rect, please check	orofit corporation appropriately:	X Public Mutu	al	corporation as indicated.	
(7) Signature: Electronic	:		(8)	Date: 09/11/2013 1:30	PM	
(9) Type/Print Name: KIM	PRIDGEN		(10)	Title: CONTROLLER		

## Attachment A-6 Deed

This instrument was prepared by Yost and Balthrop, Attorneys Springfield, Tennessee , Map 93, Parcels 36 and 35.01

Send Tax Bill To; Jesse;Holman Jones Hospital, a Tennessee not for profit Corporation

THIS DEED OF CONVEYANCE, executed and delivered by Muriel R. Watson, a widow, hereinafter called the grantor, to Jesse Holman Jones Hospital, a Tennessee not for profit Corporation, hereinafter called the grantee;

WITNESSETH: That, for the consideration of One (\$1.00) Dollar, cash and other valuable consideration, receipt of which is hereby acknowledged. I, the said grantor, have this day bargained and sold and do by these presents hereby sell, transfer and convey unto the said grantee, successor and assigns, certain tracts or parcels of land situate in the 9th Civil District of Robertson County, Tennessee, described as follows, to-wit:

TRACT NO. 1: BEGINNING at a concrete monument (new) in the easterly margin of U. S. Highway #431, the northwest corner of a tract of land which belongs to Larry Eden, having a deed reference in Deed Book 207, page 56, Registers' Office for Robertson County, Tennessee, the most westerly southwest corner of this tract and continuing as follows, N 34 deg. 09' 16" E, 211.24 feet to a concrete monument (old); thence N 24 deg. 54' 54" E, 202.08 feet to a concrete monument (new); thence N 45 deg. 56' 39" E, 395.65 feet to a concrete monument (old); thence N 45 deg. 58' 37" E, 249.72 feet to a concrete monument (old) at the intersection of the easterly margin of U. S. Highway #431 and the southwesterly margin of Watson Road; thence S 44 deg. 50' 54" E, 219.11 feet to a concrete monument (old); thence S 42 deg. 01' 36" E, 370.74 feet to a concrete monument (new) in the southwesterly margin of Watson Road; thence with a new line as follows, S 41 deg. 03' 07" W, 161.72 feet to a concrete monument (new); thence with a new line as follows, S 41 deg. 03' 07" W, 161.72 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 252.99 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 252.99 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 252.99 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 105.15 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 105.15 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 105.15 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 105.15 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 105.15 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 105.15 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 105.15 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 105.15 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 105.15 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 105.15 feet to a concrete monument (new); thence S 41 deg. 56' 44" E, 10

deg. 38' 22" W, 30.12 feet; thence 8 24 deg. 20' 46" E, 58.10 feet; thence S 19 deg. 04' 09" W, 95.97 feet; thence S 14 deg. 06' 41" W, 126.56 feet; thence 8 2 deg. 35' 56" E, 37.00 feet; thence S 17 deg. 08' 52" E, 45.46 feet; thence S 9 deg. 19' 03" E, 76.02 feet; thence S 3 deg. 33' 28" E, 53.26 feet to a point in the center of said branch marked by a witness fence post (old) on the west bank, the northeast corner to a tract of land which belongs to William A. Jackson, having a deed reference in Deed Book 223, page 249, Register's Office for Robertson County, Tennessee; thence N 61 deg. 45' 00" W, 738.36 feet to a fence post (old) in the northerly boundary of said tract of land which belongs to William A. Jackson; thence N 62 deg. 28' 38" W, 485.81 feet to a stone (old) in the northerly boundary of said tract of land which belongs to William A. Jackson, the southeast corner to a tract of land which belongs to Jehovah's Witness Church, having a deed reference in Deed Book 219, page 153, Register's Office for Robertson County, Tennessee; thence N 15 deg. 27' 31" E, passing a common corner to said tract of land which belongs to Jehovah's Witness Church and a tract of land which belongs to South Central Conference of Seventh Day Adventist, having a deed reference in Deed Book 307, page 717, Register's Office for Robertson County, Tennessee and continuing on passing a common corner to said tract of land which belongs to South Central Conference of Seventh Day Adventist and said tract of land which belongs to Larry Eden and continuing in all 729.34 feet to a concrete monument (new) the northeast corner of said tract of land which belongs to Larry Eden; thence N 73 deg. 52' 50" W, 264.94 feet to the point of beginning, containing 41.46 acres as surveyed by Richard C. Kessinger, Surveyor, Tennessee License #1038, d/b/a Kessinger & Associates, 610 South Main Street, Springfield, Tennessee, 37172, May 7, 1991, and being a portion of the property conveyed to John B. Watson, and wife, Muriel R. Watson, by T. B. Davis, et ux, in a deed of record which is recorded in Deed Book 92, page 69, Register's Office for Robertson County, Tennessee, and being all of that property which was conveyed to Muriel R. Watson by First American National Bank, Trustee, in a deed of record which is recorded in Deed Book 234, page 402, Register's Office for Robertson County, Tennessee. The said John B. Watson is now deceased survived by his widow, Muriel R. Watson, the grantor herein.

TRACT NO. 2: BEGINNING at an iron pin (old) in the southeasterly margin of Watson Road, a corner to a tract of land which belongs to Joe H. Moore, having a deed reference in Deed Book 149, page 431, Register's Office for Robertson County, Tennessee, the most northerly corner of this triangular tract of land and continuing as follows, S 49 deg. 13' 37' E, 159.95 feet to a point in the center of Huddleston's Branch marked by a witness concrete monument (old) on the northerly bank, a corner to said tract of land which belongs to Joe H. Moore; thence with the center of Huddleston's Branch as follows, N 88 deg. Ø6' 31" W, 56.85 feet; thence S 88 deg. 59' 57" W, 50.94 feet; thence S 86 deg. 16' 24" W, 75.3Ø feet; thence S 78 deg. 27' 40" W, 19.25 feet to the intersection of the center of Huddleston Branch and the center of Huddleston Branch and the southeasterly margin of Watson Road; thence with the southeasterly margin of Watson Road and a curve to the right having a radius of 55.00 feet, an arc distance of 41.12 feet, and a chord bearing of N 20 deg. 22' 12" E, 40.17 feet to a concrete monument (new); thence N 41 deg. 47' 22" E, 100.00 feet to the point of beginning, containing 0.26 acres as surveyed by Richard C. Kessinger, Surveyor, Tennessee License #1038, d/b/a Kessinger and

Associates, 610 South Main Street, Springfield, Tennessee, 37172, May 7, 1991, and being a portion of the property conveyed to John B. Watson and wife, Muriel R. Watson, by T. B. Davis, et ux, in a deed appearing of record in Deed Book 92, page 69, Register's Office for Robertson County, Tennessee. The said John B. Watson is now deceased survived by his widow, Muriel R Watson, the grantor herein.

TO HAVE AND TO HOLD the premises aforesaid, together with all the appurtenances and immunities thereto pertaining, unto the said grantee, successor and assigns, forever. The said grantor covenants with the grantee, successor and assigns: (1) That she is lawfully seized in fee of said premises; (2) That she has a good and perfect right to make this conveyance; (3) That said premises are unincumbered; (4) That she will warrant and defend the title in and to said land against the lawful claims and demands of all persons whomsoever.

TAXES for the year 1991 will be prorated as of date of deed. POSSESSION will be given as of date of deed.

Dated at Springfield, Tennessee, this  $\frac{20}{20}$  day of May, 1991.

Muriel Rwatson

STATE OF TENNESSEE, ROBERTSON COUNTY.

Personally appeared before me, the undersigned, a Notary Public in and for said county and state, the within named, Muriel R. Watson, a widow, the bargainor, with whom I am personally acquainted, (or proved to me on the basis of satisfactory evidence) and who acknowledged that she executed the within instrument for the purposes therein contained.

Witness my hand and seal of office, this 89 day of

Notory Public Baltur

y commission expires: Va

Jan. 29, 1995

STATE OF TENNESSEE,

ROBERTSON COUNTY.

command at a fair and voluntary sale Jesse Halman Ornes Howitel &

Subscribed and sworn to before me, this may 29,1991.

John M. Balthy

Notary Public or Register

18 25 1991

STATE OF TENNESSEE ROBERTSON COUNTY
The large with instrument and certificate were noted in note Book 25 Page 93 At 9:15 O'clock A M5-30-19 91 and recording and Recording Feed Book 307 Page State Tax Paid 5(2004-50 Fee 100 Recording Feed 00 Total 5 12001-50 Williams Lily Lind Receipt No. 4(6550 Register, Donothy B. Nead P.R.

## Attachment B-1 Executive Summary

## Attachment B-II-E-3 Equipment Lease

## ADDENDUM "A" TO THE PETCT MASTER SERVICES AGREEMENT

This Addendum modifies the PET/CT Master Services Agreement (the "Agreement"), fully executed on August 6, 2013, between Alliance HealthCare Services, Inc., a Delaware corporation, d/b/a Alliance HealthCare Radiology, located at 100 Bayview Circle, Suite 400, Newport Beach, California 92660 ("Alliance") and NorthCrest Medical Center, located at 100 Northcrest Drive, Springfield, Tennessee 37172 (the "Client").

The provisions of this Addendum shall become effective as of the date fully executed below. When properly executed below this Addendum shall be added to the above named Agreement.

**INCORPORATION**. This Addendum shall consist of the following documents 1) Addendum "A" and 2) Memorandum of Understanding.

Section 3 of the Agreement Cover Page, is hereby replaced in its entirety to read as follows:

#### 3 Fees

The fees exclude radiopharmaceuticals.

Notwithstanding anything to the contrary in this Agreement, all PET and PET/CT procedures performed under this Agreement shall be restricted to the use of only FDG (fluorine-18-deoxy-glucose) and such other PET radiopharmaceuticals that Alliance and Client agree in writing to use that are approved for clinical use by the Nuclear Regulatory Commission (NRC) or applicable State under agreement with the NRC.

#### FLAT DAILY FEE.

Five (5) hour half day of service	\$
Radiopharmaceutical Charge per dose	\$
Hourly overtime beyond five (5) hours that an Alliance technologist is present at the Unit Location:	\$

a) PET/CT Procedure Schedule and Radiopharmaceuticals. Client shall, no later than 11:00 p.m. each business day, provide to the designated Alliance representative a written schedule of its Radiopharmaceutical requirements for the next business day, showing times and quantities. Client may cancel without financial obligation any prescheduled doses by notifying Alliance's supplier of radiopharmaceuticals at least one (1) business day prior to shipment and such shipment does not occur. In the event that a scheduled procedure cannot be completed due to the actions of Alliance, the costs for the prescheduled radiopharmaceutical shall be borne by Alliance. In the event that the scheduled radiopharmaceutical shall be borne by the Client employees, the cost of the prescheduled radiopharmaceutical shall be borne by the Client at a rate of \$150 per dose. In the event that the scheduled procedure cannot be completed due to the "no show" or patient cancellation at the time of the procedure, the cost of the radiopharmaceutical shall be borne by the Client at a rate of \$150 per dose. Above stated fees are for FDG doses up to 15mCi. If the base dose 15mCi price to Alliance increases by ten percent (10%) or more, the cost in excess of ten percent (10%) shall be charged to Client on a dollar-for-dollar basis. Client agrees to return all shipment cartons and containers to the designated Radiopharmaceutical Supplier in the same condition and shall be responsible for material damages, normal "wear and tear" excepted.

## Section 4 of the Agreement Cover Page, is hereby replaced in its entirety to read as follows:

4 Scheduling. Alliance shall make the Unit available to the Client and any services that Alliance is obligated to provide under this Agreement, and Client agrees to accept the Unit and any such services, three (3) half days per week, five (5) hours per day. Alliance shall determine the specific service schedule.

## Section 5(a) is hereby added to the Agreement Cover Page as follows:

5(a) Term Extension. The term of this Agreement is extended for an additional thirty-six (36) months following the current expiration date of September 25, 2015. The new expiration date is September 25, 2018. This Agreement shall not automatically renew.

Except as herein above provided, no other change, amendment or modification of the Agreement is hereby intended or implied, including but not limited to any prior drafts of this Addendum that have not been fully executed. Capitalized terms used in this Addendum shall have the same meanings as are set forth in the Agreement, except as otherwise indicated in this Addendum.

Alliance and Client acknowledge that they and their respective legal counsel have had the opportunity to participate equally in the drafting of this Addendum and that in the event of a dispute, no party shall be treated, for any purpose, as the author of this Addendum nor have any ambiguity resolved against it on account thereof.

By their signatures to this Addendum, each of the signatories to this Addendum represent that they have the authority to execute this Addendum and to bind the party on whose behalf their execution is made. This Addendum constitutes the legal, valid and binding obligation of the parties enforceable in accordance with its terms.

This Addendum may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Delivery of an executed counterpart of this Addendum may be made by facsimile or other electronic transmission. Any such counterpart or signature pages sent by facsimile or other electronic transmission shall be deemed to be written and signed originals for all purposes, and copies of this Addendum containing one or more signature pages that have been delivered by facsimile or other electronic transmission shall constitute enforceable original documents. As used in this Addendum, the term "electronic transmission" means and refers to any form of communication not directly involving the physical transmission of paper that creates a record that may be retained, retrieved and reviewed by a recipient of the communication, and that may be directly reproduced in paper form by such a recipient through an automated process.

Alliance and Client have duly executed this Addendum as of the last date written below.

ALLIANCE HEALTHCARE SERVICES, INC. d/b/a ALLIANCE HEALTHCARE RADIOLOGY		NORTHCREST M	MEDICAL CENTER	
Authorized Signature Richard W. Johns EVP, General Counsel and Corporate Secretary Date:	ž.	Authorized Signatu Printed Name: Title: Date	re	
FOR CONTRACTS USE ONLY: Contract #: 007612 DO: Darrin McCall	Customer #: Requestor: 1	24244 Michael Dougherty	Client Type: Hospital	

### A fully executed document must be received prior to service commencement.

To Mail a Signed Document: Alliance HealthCare Services, Inc., ATTN: Contracts Administration Department, 100 Bayview Circle, Suite 400, Newport Beach, California 92660.

To Email a Signed Document: Contracts@allianceimaging.com

To Fax a Signed Document: 602-345-7637



### Alliance HealthCare Services Inc. Memorandum of Understanding

Date:

NorthCrest Medical Center, 100 Northcrest Drive, Springfield, Tennessee 371	72 ("Client") agrees to utilize a PET/CT scanning coach
operated by Alliance HealthCare Services Inc. or its subsidiaries ("Alliance").	The coach will be located at area adjacent to (Enter the
General location i.e. next ER, MOB:	). While the mobile PET/CT system is at
your facility, Alliance will retain responsibility for ensuring compliance with a	all regulatory requirements for safe use and handling of
radioactive materials listed in our Tennessee radioactive materials license ("Al	lliance Authorized User"), specifically:

- 1. An Alliance Authorized User will review the ordering physician's request of a PET/CT scan. An Alliance Authorized User will supervise PET/CT technical staff.
- 2. The Alliance Authorized User or RSO will ensure the PET/CT staff complies with safe use, storage and disposal of all radioactive materials according to the RAM license.
- 3. Alliance will ensure the mobile coach is secured (locked) while unoccupied.
- 4. Alliance will be responsible for and ensure documentation is completed under both NRC or state RAM licenses including:
  - a. Dose calibrator (daily constancy, accuracy, linearity and geometry) and PET/CT camera QC in accordance with Alliance procedures
  - b. End of day surveys to include PET/CT coach and state approved client injection rooms
  - c. Radio pharmaceutical ordering and receipt records
  - d. Radioactive disposal records
  - e. Patient dose records
- 5. While on site, radiopharmaceutical doses will be delivered directly to the coach and secured in the on board hot lab. This will ensure the security and safe keeping of radioactive materials.
- 6. The Alliance Authorized User will retain authority and control over patients being injected on the mobile coach or state approved client injection rooms.
- 7. An Alliance Authorized User will be immediately available in person or by telephone to the PET/CT technical staff to answer patient related questions
- 8. F-18 FDG will be supplied as a unit dose and may be ordered by the PET/CT technical staff as prescribed by the authorized user.

#### NORTHCREST MEDICAL CENTER

Authorized Signature	Date		
Printed Name:Title:		15 	
FOR CONTRACTS USE ONLY: Contract #: 007612 DO: Darrin McCall	Customer #: 24244 Requestor: Michael Do	Client Type: Hospital ougherty	



### POSITRON EMISSION TOMOGRAPHY/COMPUTED TOMOGRAPHY (PET/CT) MASTER SERVICES AGREEMENT

This POSITRON EMISSION TOMOGRAPHY/COMPUTED TOMOGRAPHY ("PET/CT") Master Services Agreement (the "Agreement") is made effective as of the date fully executed below between Alliance HealthCare Services, Inc., a Delaware corporation, d/b/a Alliance Imaging, located at 100 Bayview Circle, Suite 400, Newport Beach, California 92660 ("Alliance") and NorthCrest Medical Center, a Tennessee not for profit corporation, located at 100 Northcrest Drive, Springfield, Tennessee 37172 (the "Client").

- 1. UNIT LOCATION (the "Unit Location"). If no address is listed in this Section, the Unit Location address shall be Client's address that is listed above.
- 2. UNIT DESCRIPTION: mobile PET/CT system (or a reasonably comparable system).
- FEES.

The fees exclude radiopharmaceuticals.

FLAT DAILY FEE.

Five (5) hour half day of service

\$3,000\_\_\_\_

Radiopharmaceutical charge per dose

\$150

Hourly overtime beyond five (5) hours that an Alliance technologist is present at the Unit Location

\$300\_\_\_\_

- a) PET/CT Procedure Schedule and Radiopharmaceuticals. Client shall, no later than 11:00 p.m. each business day, provide to the designated Alliance representative a written schedule of its Radiopharmaceutical requirements for the next business day, showing times and quantities. Client may cancel without financial obligation any prescheduled doses by notifying Alliance's supplier of radiopharmaceuticals at least one (1) business day prior to shipment and such shipment does not occur. In the event that a scheduled procedure cannot be completed due to the actions of Alliance, the costs for the prescheduled radiopharmaceutical shall be borne by Alliance. In the event that the scheduled procedure cannot be completed due to the actions of the Client employees, the cost of the prescheduled radiopharmaceutical shall be borne by the Client at a rate of \$150 per dose. In the event that the scheduled procedure cannot be completed due to the "no show" or patient cancellation at the time of the procedure, the cost of the radiopharmaceutical shall be borne by the Client at a rate of \$150 per dose, provided, however, Alliance agrees not to charge Client for up to one (1) "no show" or patient cancellation FDG charge per month. Above stated fees are for FDG doses up to 15mCi. If the base dose 15mCi price to Alliance increases by ten percent (10%) or more, the cost in excess of ten percent (10%) shall be charged to Client on a dollar-for-dollar basis. Client agrees to return all shipment cartons and containers to the designated Radiopharmaceutical Supplier in the same condition and shall be responsible for material damages, normal "wear and tear" excepted.
- 4. SCHEDULING. Alliance shall make the Unit available to the Client and any services that Alliance is obligated to provide under this Agreement, and Client agrees to accept the Unit and any such services, one half (1/2) day per week, five (5) hours per day. Alliance shall determine the specific service schedule.
- 5. TERM. The initial term of this Agreement shall be for twenty-four (24) months commencing upon delivery of the Unit to Client (the "Commencement Date") anticipated to be on or about August 2013. Fees under this Agreement shall begin to accrue on the Commencement Date. After the initial term, this Agreement shall automatically renew for successive terms, each of which shall be equal to the length of the initial term, unless either party notifies the other to the contrary in writing at least one hundred eighty (180) days prior to scheduled expiration. This Agreement shall not automatically renew.

6. INCORPORATION. This Agreement shall consist of the following documents: (1) the cover page(s) to this Agreement; and (2) General Terms and Conditions, which is attached hereto and incorporated herein.

Alliance and Client have duly executed this Agreement as of the last date written below.

ALLIANCE HEALTH	ICARE SERVICES, INC.	NORTHCREST MEDICAL CENTER	
d/b/a ALLIANCE U	AGING		
SIN	B		
Authorized Signature	/	Authorized Signature	
Richard W. Johns	/	Printed Name: Kondy DAVIS	
EVP, General Counsel	and Corporate Secretary	Title: SryB	
Date:	Trugast 6,2013	Date: _7/80/15	
Telephone No.	(949) 242-5300	Telephone No. 615-384-1601	
Federal Tax ID No.	33-0239910	Federal Tax ID No. 62 - 16465 88	



FOR CONTRACTS USE,Q	YLY:	Outsitel	
Contract #: ()(	Customer #:	09099	Client Type: Hospital
DirSales/East:	SDO/East: TGaston	DO: Darrin McCall	Requestor: Michael Dougherty

### A fully executed document must be received prior to service commencement.

To Mail a Signed Document: Alliance HealthCare Services, Inc., ATTN: Contracts Administration Department, 100 Bayview Circle, Suite 400, Newport Beach, California 92660.

To Email a Signed Document: Contracts@allianceimaging.com

To Fax a Signed Document: 602-345-7637

## **GENERAL TERMS AND CONDITIONS**

I. EQUIPMENT AND SERVICES.

1.1 The Unit. Alliance shall provide a PET/CT system described in the cover page(s) to this Agreement (the "Unit"). If the Unit described is deemed in Alliance's discretion to be unavailable, a reasonably comparable Unit may be substituted.

1.2 Personnel.

a) Provision of Personnel. Alliance shall provide the services of technical personnel to operate the Unit and a patient coordinator to assist the technical personnel in the operation of the Unit,] as appropriate for Client's procedure volume. Alliance shall ensure that all services provided by Alliance's personnel shall be within the scope of his/her respective duties. Nothing in this Agreement shall be construed to obligate Alliance to violate any applicable employment laws or regulations, and Alliance personnel shall be entitled to take all breaks as required under any applicable

laws or regulations.

b) Non-Solicitation. Client agrees not to hire or contract with any Alliance employee during the term of this Agreement, including renewals, and for a period of one (1) year after services cease (collectively, the "Non-Solicitation Period"), without Alliance's prior written consent. Alliance and Client hereby agree that in the event of a breach of this provision damages shall be difficult to calculate and therefore agree Alliance shall be entitled to receive six (6) times the monthly average salary of such employee for the past twelve months (or such shorter period as the employee may have been employed by Alliance). Alliance and Client agree that the aforementioned amounts are reasonable and shall constitute liquidated damages and not a penalty.

c) Disclosure of Personnel Information. Notwithstanding anything to the contrary in this Agreement, Client agrees, for as long as Alliance remains a Joint Commission-accredited organization, that Client shall not need to independently verify, and shall not require any oral information or written documentation concerning the credentialing, education, training, evaluation, or competencies related to any of Alliance's technical personnel beyond the following, which documentation set composition may be modified from time-to-time by Alliance in its reasonable discretion and which Alliance will provide to Client in writing upon request: (a) a description of the competencies related to Alliance's technical personnel who provide services on the Unit; (b) copies of any licenses and certifications for such personnel; (c) evidence that all vaccination test(s) required by applicable State law or regulation have been taken by such personnel; (d) a job description for the technologist(s) providing services on the Unit; and (e) a letter from Alliance's Vice President of Human Resources or designee attesting that criminal investigation background checks have been performed for each of Alliance technical personnel who provide services on the Unit and that such personnel meet the requirements to be employed by Alliance. Alliance shall not be obligated to provide any background check report, drug test report or result, or job performance evaluation for any of Alliance's technical personnel. Further, notwithstanding anything to the contrary in this Agreement, in the event of a Joint Commission survey of Client, Alliance, upon request by the Joint Commission surveyor, shall have the personnel file of Alliance's technical personnel accessible to the surveyor only for review as may be required by the Joint Commission.

d) Confidentiality of Personnel Information. Client acknowledges that all verifications, documents, electronic data, and other materials concerning

Alliance personnel that Alliance provides or makes accessible in connection with this Agreement (collectively, "Confidential Personnel Information") are valuable property of Alliance, and Client undertakes that, during the term of this Agreement and thereafter until such time that the Confidential Personnel Information otherwise becomes publicly available other than through breach of this Section, Client shall: (i) treat the Confidential Personnel Information as trade secret and confidential assets of Alliance's business; (ii) not disclose (directly or indirectly, in whole or in part) the Confidential Personnel Information to any third-party except with the prior written consent of Alliance or when and if properly disclosed in connection with the Centers for Medicare and Medicaid Services ("CMS"), The Joint Commission, or other applicable federal and state compliance surveys, audits, reviews and record requests or as required by law; (iii) not use (or in any way appropriate) the Confidential Personnel Information for any purpose other than compliance with CMS, The Joint Commission, or other applicable federal and state requirements and/or as required by law; (iv) limit the dissemination of and access to the Confidential Personnel Information to Client's officers, managers, employees, agents, attorneys, consultants, professional advisors or representatives on a need to know basis as may reasonably be required for the performance of Client's compliance obligations outlined above, provided Client ensures that such individuals and entities observe all the confidentiality obligations set forth in this Section; (v) be entitled to use the Confidential Personnel Information only in good faith for the legitimate conduct of its business activities, and shall not in any case use such Confidential Personnel Information to gain a competitive advantage or for purposes unrelated to compliance with CMS, The Joint Commission, or other applicable federal or state requirements; and (vi) return any and all Confidential Personnel Information to Alliance promptly upon the termination or expiration of this Agreement, including but not limited to all such materials, documents, information and electronic data, regardless of how stored or maintained, and including all originals and copies.

1.3 Maintenance. Alliance shall use reasonable efforts to cause the Unit to be maintained in good operating condition. Alliance may do so through the purchase of a maintenance contract from the Unit manufacturer or otherwise, in its discretion. Client shall be responsible for maintaining in good and safe working order any equipment, including but not limited to a gurney or wheelchair, that Client provides to Alliance for Alliance's use under this Agreement.

SCANNING ACTIVITIES.

2.1 Unit. Client shall prepare and maintain a safe and suitable site for the Unit which complies with the manufacturer's specifications (which shall be provided by Alliance) and all applicable laws and regulations. All site costs (for example, costs of tractor/trailer access and egress, power and telephone expenses) shall be Client's responsibility. The Unit Location shall be as referenced in the cover page(s) to this Agreement. Client represents and warrants to Alliance that it currently owns or has authorization to site the Unit at the Unit Location, Further, Client further warrants and agrees that, at all times during the term of this Agreement, Client shall maintain the authorization or ownership to site the Unit at the Unit Location. Client shall indemnify and hold Alliance harmless from any damages or liability arising out of breach of the representations and warranties in this Section. Client may request in writing to Alliance that the Unit Location be

moved, in which case any such move shall be subject to Alliance's prior approval; all of the obligations under this

Section shall apply to the new Unit Location.

2.2 Power. Client shall provide electrical power to the Unit, including a dedicated power line with 200 amps and 480 volts of three-phase power. Client shall provide the power line, a lockable disconnect box and receptacle within twenty-five (25) feet of the electrical receptacle on the Unit. Notwithstanding anything to the contrary in this Agreement, Client shall be responsible for the quality of power to the Unit and any damage to the Unit due to power that does not meet such specifications or any other problems with power (e.g., sags or surges). As such, Alliance recommends that Client install a line conditioner or surge protector to prevent any problems with power to the Unit. Client shall promptly report to Alliance any problems with power to the Unit.

2.3 Phone and Connectivity. Client shall provide the Unit with a voice telephone line, a dedicated fax compatible telephone line and a RJ-45 ethernet broadband line with an automatic IP address assignment using Dynamic Host Control Protocol ("DHCP") and a proxy-less connection to the

internet.

2.4 Operation. The Unit shall be operated only by employees or subcontractors of Alliance. Notwithstanding anything to the contrary in this Agreement, Client shall not be entitled to use the Unit, directly or through a subcontractor, during any period of suspension of this Agreement, following termination of this Agreement, or following expiration of this

Agreement.

2.5 Medical Director. Client shall appoint a qualified and licensed physician to act as Medical Director hereunder, along with another such physician to act in his absence (the "Medical Director"). Client shall ensure that all orders for diagnostic procedures under this Agreement are made only by a licensed physician or another licensed healthcare provider authorized by applicable federal and/or state law. Client shall be solely responsible for all activities which constitute the practice of medicine (for example, providing medical advice to patients in connection with PET/CT procedures and the supervision of the injection of radiopharmaceutical agents). Client shall obtain any written consents from patients that are required by the USFDA, state or local law or prudent medical practice. Alliance shall be entitled, but not obligated, to use its own patient consent and screening questionnaire forms to supplement patient forms provided by the Client. Client shall have full responsibility for all medical care, supervision services, and advice provided to patients, in accordance with applicable laws, rules and regulations. All medical care shall be provided under the ultimate supervision of the Medical Director.

2.6 Medical Supplies; Hazardous Waste Disposal; Emergency Care. Client shall provide all medical supplies which may be required (including film and film processing, gowns, medications and radiopharmaceutical agents). Client agrees to dispose of all hazardous waste relating to the services under this Agreement that Alliance provides to Client from time-to-time. Client shall ensure the immediate availability at all times of equipment and personnel to treat patients who require emergency or other medical care (including a cardiac monitor, a fresh oxygen supply, an

aspirator and a defibrillator).

2.7 Patient Handling. Client shall be responsible for the prompt and orderly pick up and delivery of patients to and

from their rooms or other designated areas.

2.8 Patient Log. Alliance shall maintain a log of all procedures performed on the Unit. Client shall be provided with copies of the log upon request.

2.9 Modifications. Client shall not modify or alter the Unit without Alliance's prior written consent. Client shall not allow any portion of the Unit to become permanently attached to real property. Client agrees that, upon request, Client shall sign any documents (e.g., a UCC financing statement) evidencing a first priority security interest, mortgage, or assignment in favor of any company (e.g., the original equipment manufacturer) providing financing to Alliance for the Unit. Nothing in this Section, shall affect any ownership interest that Client has in its own property.

2.10 Scheduling. Client shall use all reasonable efforts to schedule its patients consecutively from the beginning of each service day to minimize unutilized scanning time and to prescreen patients for conditions unsuitable for PET/CT procedure. Notwithstanding anything to the contrary in this Agreement, Alliance reserves the right to release its technical personnel and/or Unit from Client's Unit Location after the completion of the last scheduled procedure on any given service day in which no more patients are scheduled provided the technologist(s) have verbally confirmed with the Client that no additional patients shall be added to the schedule for that particular service day.

2.11 Notification of Physicians. Client shall notify its staff of physicians of the availability of the Unit and shall use reasonable efforts to educate the community about the

Unit.

2.12 Exclusivity. Client agrees to use Alliance solely for all of its PET/CT and PET needs, except for an emergency where the use of Alliance's service is impractical, when the patient expresses a desire to receive PET or PET/CT services from a different provider, when the patient's insurance determines that the patient must receive PET or PET/CT services from a different provider, or when the referral is not in the best medical interest of the patient in the physician's judgment. Client, on behalf of itself, its parent, its subsidiaries, owners and/or corporate affiliates (including but not limited to any entity in which Client has an ownership interest) agree during the term of this Agreement, not to own, permit, lease, manage, or invest in any PET/CT or PET system or engage any entity besides Alliance to provide Client with PET/CT or PET services. Notwithstanding anything to the contrary in this Agreement, this Section shall remain in effect during any period in which the Agreement is suspended. Further, in the event this Agreement terminates due to a Client default under this Agreement, this Section shall survive such termination and remain in effect for the remainder of the then-current term of the Agreement had the Agreement not early terminated.

2.13 Access to Records. If the value or cost of services rendered pursuant to this Agreement is \$10,000 or more over a 12-month period, in accordance with Section 1861(v)(1)(1) of the Social Security Act, Alliance agrees that until the expiration of four (4) years after the furnishing of services under this Agreement, Alliance shall make available, upon written request by the Secretary of the U.S. Department of Health and Human Services, or upon request by the Comptroller General of the United States, or any of their duly authorized representatives, such contracts, books, documents, and records of Alliance that are necessary to certify the nature and extent of such costs. If Alliance carries out any of the duties of this Agreement through a subcontract with another organization and the value or cost of such subcontracted services is \$10,000 or more over a twelve (12) month period, such subcontract shall contain a clause to the same effect as this provision.

2.14 Licenses. Client shall obtain and maintain all required licenses and regulatory approvals necessary to operate the Unit at Client's premises. Alliance shall reasonably

cooperate to assist Client to obtain such licenses and approvals. Alliance will possess all necessary State and federal radioactive materials licenses. Alliance will adhere to all licensing requirements applicable to radioactive materials and will be responsible for the safe and proper use of radioactive materials in compliance with applicable laws.

2.15 Taxes. All taxes, if any (for example, sales, use or similar taxes), on the services hereunder shall be the responsibility of Client (other than taxes on Alliance's net

income from the services hereunder).

2.16 Professional Interpretations. Client shall need to engage a radiologist to provide interpretations of PET/CT procedures for Client patients. Alliance shall not be responsible for providing any such interpretations.

2.17 Patient Records. Client shall maintain patient records for each patient who receives procedures performed

under this Agreement.

2.18 Customer Support. Alliance shall provide the

following:

 a) Radiopharmaceuticals. Assistance to Client in obtaining, licensing and handling procedures for

radiopharmaceuticals.

- b) Billing. Information regarding PET/CT billing codes, information and reimbursement data provided, however, that Client shall not be entitled to rely upon any such information by Alliance and shall confirm such information independently by contacting either the local Medicare carrier/intermediary, or seeking the advice of legal counsel or a reimbursement consultant. Client agrees to comply with relevant billing and documentation requirements.
- FEES AND BILLING. Client shall pay Alliance fees that are set forth in the cover page(s) to this Agreement. All fees for a billing period shall be due and payable within fifteen (15) days of the last day of such period. Alliance shall invoice Client once each month. Client shall pay a late fee of one and one-quarter percent (1 1/2 %) or the maximum legal rate, whichever is less, on all balances outstanding more than fifteen (15) days beyond the due date compounded and assessed for each month that such balances are past due. Alliance may adjust fees effective on each anniversary of the Commencement Date by the percentage increase for the Medical Care Services component of the Consumer Price Index for all Urban Consumers (CPI-U) as recorded by the Department of Labor Index for the then most recently available twelve month period. Client shall be responsible for all billings to Client patients and/or third party payors for PET/CT procedures performed on the Unit. Client's obligation to pay Alliance compensation in accordance with the provisions of this Agreement shall not be dependent upon Client's billing and collection of patient and/or third party payor accounts receivable. Alliance shall not bill, and Alliance shall not cause bills to be submitted to, any patient or third party payor for PET/CT procedures performed on the Unit. All billings for Client patients shall be in the name of Client, and Client shall not subcontract any of the services under this Agreement or the Unit to any third party. Both parties agree that Alliance is providing its services set forth on this Agreement "under arrangement" with Client, such that upon Client's receipt of payment from the Medicare program for PET/CT procedures performed in the Unit, the liability of the beneficiary or any other person to pay for such services shall be fully discharged.
- 4. TERM. The term shall be as specified in the cover page(s) to this Agreement. The term of the Agreement shall also be extended coterminously with any period(s) services are

suspended. In the event this Agreement terminates or expires and Client continues to accept services, the terms and conditions of this Agreement shall apply to the provision of services and Client shall be bound to accept such services until and unless Client shall terminate such extension upon further written notice to Alliance of not less than ninety (90) days. During any such term extension, the fees paid to Alliance shall be increased 10%.

5. SCHEDULING. Alliance shall make the Unit available to Client according to the schedule specified on the cover page(s) to this Agreement. Alliance personnel will not be available during the following holidays observed by Alliance: New Years Day, Memorial Day, Fourth of July, Labor Day, Thanksgiving Day, and Christmas Day. The day of service begins upon initiation of the setup procedures for the Unit and ends upon completion of the shutdown procedures for the Unit.

## 6. INSURANCE, INDEMNIFICATION.

6.1 Insurance.

a) Alliance. Alliance shall maintain insurance covering all risks of physical loss or damage to the Unit, comprehensive general liability and professional liability covering the conduct of its employees, all in amounts and subject to deductibles that are customary in the industry.

b) Client. Client shall maintain comprehensive general and professional liability insurance covering the Client, its employees, staff and physicians and shall require the Medical Director and other physicians who interpret or report on procedures performed on the Unit to maintain professional liability insurance. All such insurance shall be in amounts and with deductibles that are customary in the industry. Client shall bear the risk of loss or damage to the

Unit from Client's negligent actions or omissions.

6.2 Indemnification. Each party hereto shall indemnify and hold the other party harmless from and against any and all liability, loss, damage, cause of action, cost or expense (including reasonable attorney's fees) arising out of, or in any way connected with, any negligent or intentional act or failure to act, any breach of any representation or warranty under this Agreement, or any other wrongful conduct by the respective party, its members, agents, employees or subcontractors in the performance of its duties under this Agreement. The parties agree that upon receipt of a claim or demand for which a party is entitled to indemnification, the indemnified party shall: (i) provide the indemnifying party with prompt written notice of any indemnifiable claim; (ii) permit the indemnifying party to assume sole control of the defense with counsel selected by the indemnifying party; (iii) furnish the indemnifying party with all documents and information within the possession, custody, or control of the indemnified party relating to such claim; (iv) reasonably cooperate with the indemnifying party and its counsel; and (v) not enter into any oral or written negotiation, settlement, or compromise of any indemnifiable claim without the indemnifying party's prior written consent. In the event the indemnifying party defends the indemnifiable claim, it may do so under a reservation of its rights to cease the defense of the claim at a later date (upon reasonable prior written notice to the indemnified party) in the event it is determined that the indemnifying party has no obligation to defend or indemnify the claim.

### 7. GENERAL.

7.1 Independence. Alliance is an independent contractor of Client, and this Agreement is a contract for

services, not a lease. No agency, employment, partnership or joint venture is intended to be created by this Agreement. Neither Alliance nor Client shall take any action or position which is inconsistent with those descriptions of the

relationship.

7.2 Remedies. Alliance shall not be responsible for failure to provide services as a result of conditions caused by Client. NOTWITHSTANDING ANYTHING IN AGREEMENT TO THE CONTRARY, ALLIANCE SHALL NOT BE RESPONSIBLE FOR INDIRECT, INCIDENTAL, PUNITIVE, CONSEQUENTIAL, OR OTHER SPECIAL DAMAGES THAT CLIENT MAY INCUR EXPERIENCE IN CONNECTION WITH THIS AGREEMENT OR THE SERVICES PROVIDED BY HOWEVER CAUSED AND UNDER THEORY OF LIABILITY, EVEN IF ALLIANCE, WHATEVER ALLIANCE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

7.3 Waiver. No waiver of any provisions of this Agreement or a breach thereof shall be valid or enforceable unless in writing and signed by both parties. The waiver by either party of any breach of any term, covenant, warranty, or condition contained in this Agreement shall not be deemed to be a waiver of any subsequent breach of the same or any other term, covenant or condition contained in this Agreement.

7.4 Notices. All notices required or permitted under this Agreement must be in writing and delivered either by reputable national or international overnight delivery service or by registered or certified U.S. mail (postage prepaid with return receipt requested). The initial addresses of the parties to which notice must be sent are listed on the cover page(s) to this Agreement. Notices to Alliance shall be sent to the attention of General Counsel. If notice is delivered by reputable national or international overnight delivery service, then notice shall be effective one (1) business day after deposit with the carrier. If notice is delivered by registered or certified U.S. mail (postage prepaid with return receipt requested), then notice shall be effective five (5) business days after deposit with the carrier. Either party may change its address for notice by notifying the other by a

permitted method of giving notice.

7.5 Governing Law; Venue. The laws of the State of California (without giving effect to its conflicts of law provisions) shall govern all matters arising out of or relating to this Agreement, including, but not limited to, its validity, interpretation, performance, enforcement, and construction. Each party hereto hereby irrevocably and unconditionally: (i) consents to submit to the exclusive jurisdiction of the courts of the State of California, and of the United States, located in Orange County, California for any action, suit, or proceeding arising out of or relating to this Agreement (and each party hereto hereby irrevocably and unconditionally agrees not to commence any such action, suit, or proceeding except in such courts); (ii) waives any objection to the laying of venue of any such action, suit, or proceeding in any such courts; and (iii) waives and agrees not to plead or claim that any such action, suit, or proceeding brought in any such court has been brought in an inconvenient forum.

7.6 Entire Agreement; Amendment. This Agreement is the parties' entire understanding and supersedes all prior agreements, oral and written, with respect to the subject matter of this Agreement, and no party will be bound by any representation, covenant, term, or condition other than as expressly stated in this Agreement. No statements, promise, or representations have been made by any of the Parties to any other, and no consideration has been offered, promised, expected or held out other than as is expressly provided

herein. This Agreement may not be amended except by written agreement signed by both parties to this Agreement. No handwritten changes to this Agreement shall be enforceable unless such changes are initialed by both parties to this Agreement. This Agreement is binding upon and will inure to the benefit of the parties and their respective heirs,

personal representatives, successors, and assigns.

7.7 Successors and Assigns. Alliance may assign this Agreement. Client may not assign this Agreement without the prior written consent of Alliance. Client agrees that this Agreement may be performed, in whole or part, by a parent, subsidiary, or affiliate of Alliance and further consent shall not be required. Alliance may also assign the proceeds of this Agreement. Client shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, sale of property or stock, liquidation, or otherwise) to all or a substantial portion of its assets, by agreement in form and substance reasonably satisfactory to Alliance, to expressly assume and agree to perform Client's obligations under this Agreement.

7.8 Third Parties. Nothing in this Agreement creates, or will be deemed to create, any third party

beneficiaries of or under this Agreement.

7.9 Attorney Fees. In any dispute arising out of this Agreement (whether litigation is involved or not) or in the event that either party must take action to collect fees or enforce rights, the prevailing party shall be entitled to reimbursement of its expenses, including court expenses and lawyers' fees.

Certain Events. Neither party will be responsible for any failure or delay in its performance under this Agreement (other than financial obligations including payment of amounts due) if such failure or delay is the result of any: labor dispute; act of God; inability to obtain labor or materials; accident; future law, regulation, ordinance or requirement of any government or regulatory agency; or any

other event which is beyond its reasonable control.

7.11 Confidentiality. Client acknowledges and agrees that this Agreement is highly confidential and proprietary to Alliance and Client agrees that neither it, nor any of its employees, contractors, or physicians, shall disclose in any manner the terms, provisions, pricing or any other information contained in this Agreement (or any related proposal) to any third party. Further, Client shall ensure that neither it nor any of its employees, contractors, or physicians disclose any of Alliance's policies, procedures, or other confidential information that Client or its employees, contractors, physicians receives, except to the extent required by an accreditation organization to which Client is subject or a

governmental entity.

7.12 Accreditation. Alliance and Client agree to set standards of care and quality that comply with the Joint Commission and the American College of Radiology (ACR). Alliance and Client shall reasonably cooperate in all phases of applying, scheduling, preparing and executing surveys or inspections by the Joint Commission and ACR, as needed. Client shall be responsible for costs associated with ACR accreditation. These costs shall include but are not limited to physicist evaluation, phantom hardware and application fees. Alliance shall provide the technical expertise and act as the liaison on Clients behalf to obtain ACR accreditation. Alliance shall comply with ACR guidelines in order to maintain ACR accreditation in good standing. Both parties agree to work reasonably cooperatively to implement changes, correct deficiencies or establish policies required and/or recommended by the inspecting agencies as applicable.

Alliance shall provide Client with a copy of Alliance's Joint Commission accreditation certificate and most current patient satisfaction survey results, as requested by Client.

7.13 Policies and Procedures. Client agrees that Client shall comply with all of Client's policies and procedures, and Client agrees to indemnify and hold Alliance harmless from and against any and all liability, loss, damage, cause of action, cost or expense (including reasonable attorney's fees) arising out of, or in any way connected with, Client's failure to fully comply with Client's policies and

procedures.

7.14 Severability. In the event that any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and the application of such provision to other persons or circumstances shall be interpreted so as reasonably to effect the intent of the parties hereto. The parties hereto further agree to use their commercially reasonable efforts to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

7.15 Credit Checks. By signing the cover page(s) to this Agreement, Client hereby authorizes Alliance, as determined necessary by Alliance in Alliance's discretion upon such signature and from time-to-time during the term of the Agreement, to (i) obtain a standard factual credit data report concerning Client through a credit reporting agency or any other similar agency (a "Credit Reporting Agency") chosen by Alliance, and (ii) release to such Credit Reporting Agency any credit applications, financial information, or any other information of Client. Further, Client hereby agrees to provide Alliance with all appropriate credit applications and

paperwork necessary to effectuate the above.

7.16 Construction. Every term and provision of this Agreement is to be construed simply according to its fair meaning and not strictly for or against any party. No provision of this Agreement is to be interpreted as a penalty upon, or a forfeiture by, any party to this Agreement. The parties acknowledge their right to separate legal counsel, and agree to obtain any appropriate advice or opinions about this transaction from their respective counsel. The parties acknowledge that they and their respective legal counsel have had the opportunity to participate equally in the drafting of this Agreement and that in the event of a dispute, no party shall be treated, for any purpose, as the author of this Agreement nor have any ambiguity resolved against it on account thereof.

7.17 Execution. By their signatures on the cover page(s) of this Agreement, each of the signatories to this Agreement represent that they have the authority to execute this Agreement and to bind the party on whose behalf their execution is made. This Agreement constitutes the legal, valid and binding obligation of the parties enforceable in

accordance with its terms.

7.18 Counterparts. This Agreement may executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Delivery of an executed counterpart of this Agreement may be made by facsimile or other electronic transmission. Any such counterpart or signature pages sent by facsimile or other electronic transmission shall be deemed to be written and signed originals for all purposes, and copies of this Agreement containing one or more signature pages that

have been delivered by facsimile or other electronic transmission shall constitute enforceable original documents. As used in this Agreement, the term "electronic transmission" means and refers to any form of communication not directly involving the physical transmission of paper that creates a record that may be retained, retrieved and reviewed by a recipient of the communication, and that may be directly reproduced in paper form by such a recipient through an automated process.

#### TERMINATION.

#### 8.1 Termination.

a) Material Breach. Alliance or Client may terminate this Agreement if the other party breaches any material covenant, term or provision of this Agreement and the material breach is not cured within sixty (60) days following provision of notice to the breaching party specifying the alleged material breach.

b) Bankruptcy. Alliance or Client may terminate this Agreement if the other party commits or suffers (voluntarily or involuntarily) an act of bankruptcy,

receivership, liquidation or similar event.
8.2 Termination, Alliance. Alliance may terminate

this Agreement or suspend service if:

a) Payment Default. Client fails to make any payment to Alliance when due and such failure continues for ten (10) days following notice to Client. In the case of any payment default, Alliance may, without notice, cease providing services hereunder after three (3) days following a payment due date should it feel insecure with respect to

Client's ability or willingness to make payment.
b) Inability to Cover Costs. Alliance is unable to cover its costs on the services provided hereunder, provided that the parties have negotiated in good faith to modify the terms of this Agreement to eliminate such inability and a period of sixty (60) days has elapsed since Alliance originally notified Client of such condition. In lieu of termination, Alliance may reduce the number of days of service provided.

c) Mobile Route. Alliance's mobile route for service on the Unit to all Alliance clients (including but not limited to Client) should fall below four full days of

contracted service per week.

8.3 Default. In the event that this Agreement terminates due to a default by Client under Section 8.1(a), Section 8.1(b), Section 8.2(a), or Section 9.4 of this Agreement, Alliance may take any action at law or in equity, including, but not limited to, collecting from Client payments then due and to become due under the remaining term of the Agreement had the Agreement not early terminated. The foregoing remedies are in addition to any provided by law. Neither party shall have obligation to exercise any remedy and the exercise of the remedy shall not release the parties for any obligation hereunder. All remedies shall be cumulative, and action on one shall not constitute an election or waiver of any other right to which either party may be entitled.

8.4 Inability to Cover Costs. Client may terminate this Agreement if Client is unable to cover its direct costs (i.e., the fees Client pays to Alliance hereunder) on the aggregate services provided hereunder to all of Client's patients measured over a three (3) month period, provided that: (i) Client notifies Alliance of such inability; (ii) Client provides Alliance with documented proof of Client's inability to cover Client's direct costs over the three (3) month period immediately preceding such provision of notice to Alliance (i.e., a spreadsheet listing, for each procedure provided by Alliance under this Agreement for which Client has received reimbursement from the payor during the

aforementioned three (3) month period, (a) the name of the patient, (b) the date of service, (c) the fee paid to Alliance, (d) the CPT code billed, (e) the name of the payor, (f) the claim submission date, (g) the claim payment date, and (h) the amount received from the payor); and (iii) Client and Alliance have negotiated in good faith to modify the terms of this Agreement to eliminate such inability to cover Client's direct costs and a period of sixty (60) days has elapsed since Client originally notified Alliance of such inability. The direct costs of procedures provided hereunder that have not been separately reimbursed by a payor (e.g., claims not billed, pending claims, procedures subject to DRG, etc.) shall not be included in the calculation to determine whether Client has been unable to cover its direct costs. During the aforementioned sixty (60) day period, Client agrees to make available to Alliance upon request access to Client's books and records to substantiate the data included in the aforementioned spreadsheet. The termination of this Agreement shall not discharge Client from any liability associated with services rendered prior to the termination of this Agreement. Client agrees that at the time of termination, all balances owed Alliance must be paid in full.

### 9. COMPLIANCE WITH LAWS.

9.1 Compliance with Current Laws. The parties agree that it is their understanding and intent that this Agreement, including any exhibits and other attachments, complies as of the effective date hereof with all applicable federal and state laws and regulations, including, but not limited to, self-referral and anti-kickback laws. Further, the parties agree that they shall comply with all such laws and regulations, as may be amended from time to time. Client represents and warrants that it has not relied on any billing or reimbursement advice that it may have directly or indirectly received from Alliance, and that Client has and shall consult with Client's own billing and reimbursement experts and attorneys with respect to billing under this Agreement. Further, Client warrants and agrees that, throughout the term of this Agreement, Client shall comply with all applicable billing laws, regulations and rules, as may be amended from time to time.

9.2 No Inducement. This Agreement has been negotiated in good faith through arms length negotiations. Nothing contained in this Agreement, including any compensation paid or payable, is intended or shall be construed: (i) to require, influence or otherwise induce or solicit either party regarding referrals of business, or recommending the ordering of any items or services, of any kind whatsoever to the other party or any of its affiliates, or to any other person, or otherwise generate business between the parties, or (ii) to interfere with a patient's right to choose his

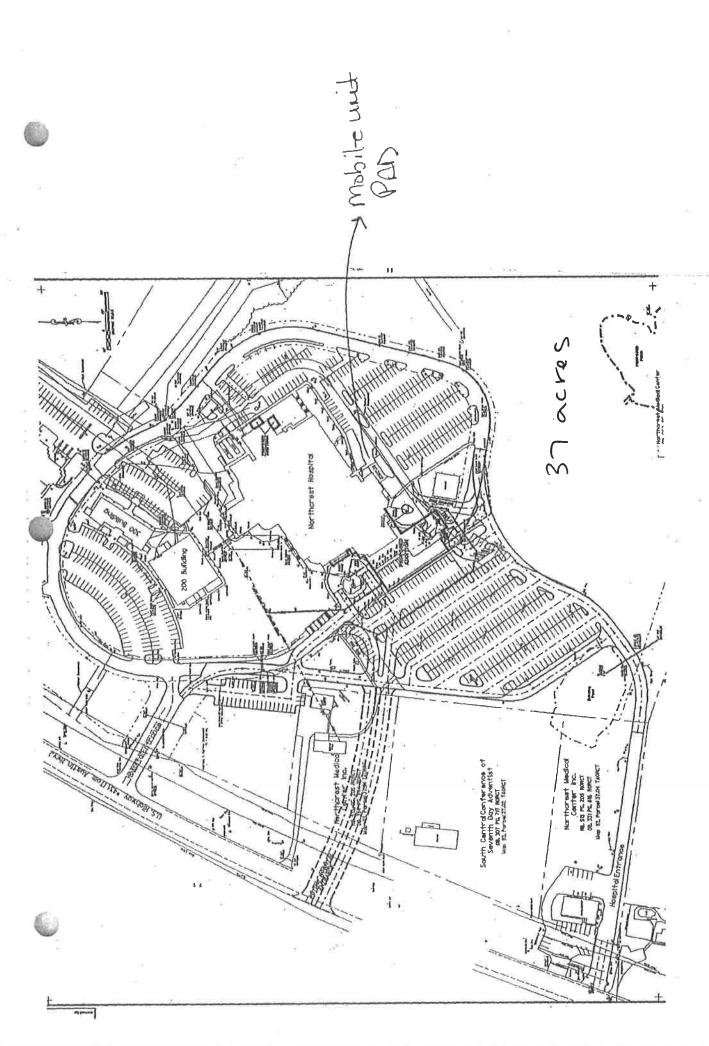
or her own health care provider, or with a physician's medical judgment regarding the ordering of any items or services.

9.3 Change in Law. If any change in any applicable federal, state or local government laws, rules or regulations (each, a "Law" and, collectively, "Laws") would render unlawful the conduct under this Agreement of either party hereto, then the parties shall negotiate in good faith to restructure the business arrangement between the parties to conform with the then existing Laws. If the parties have not reached an agreement regarding the material terms of the restructured business arrangement within forty-five (45) days of the change in such Law or by the effective date of such Law, whichever is sooner, then this Agreement may be cancelled by either party upon thirty (30) days' written notice to the other party or upon such effective date, whichever is sooner.

9.4 No Federal Health Care Program Exclusion. Each party represents and warrants to the other party that: (i) neither the representing party nor any of its officers, directors, or employees or contractors providing services under this Agreement are currently excluded, debarred, or otherwise ineligible to participate in the Federal health care programs as defined in 42 U.S.C. Section 1320a-7b(f) (the "Federal health care programs"); (ii) neither the representing party nor any of its officers, directors, or employees or contractors providing services under this Agreement have ever been convicted of a criminal offense related to health care; and (iii) the representing party is not aware of any circumstances which may result in the representing party or any of its officers, directors, or employees or contractors providing services under this Agreement being excluded from participation in the Federal health care programs. This shall be an ongoing representation and warranty during the term of this Agreement, and each party shall immediately notify the other party of any change in status of the representation and warranty set forth in this Section. In the event a party or any of its officers, directors, or employees or contractors providing services under this Agreement become excluded, debarred, or otherwise ineligible to participate in the Federal health care programs, that party shall be considered in default of this Agreement, and the other party may immediately terminate this Agreement for cause; provided, however, a party can prevent such termination if that party is not excluded, debarred, or otherwise ineligible to participate in the Federal health care programs and immediately terminates its relationship with any of its officers, directors, or employees or contractors providing services under this Agreement who become excluded, debarred, or otherwise ineligible to participate in the Federal health care programs.

[END OF GENERAL TERMS AND CONDITIONS]

## Attachment B.III-A Plot Plan



## Attachment B-IV Floor Plan Mobile PET/CT Unit



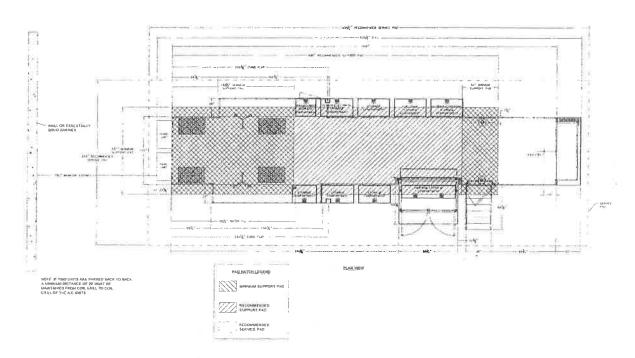


Figure 2: Plan Layout

This information is the property of Oshkosh Specialty Vehicles and is considered to be confidential. The contents may not be used, either partially or wholly, for any purpose inconsistent with which it was produced, Also, this information may not be reproduced or disclosed without prior express consent,

## Attachment C-Need Review Standards and Criteria 6-A FDA Certification Letter



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

## JUN 1 5 2004

Mr. David Duersteler Safety and Regulatory Engineering GE Healthcare Technologies General Electric Company P.O. Box 414 MILWAUKEE WI 53201 Re: K041220

Trade/Device Name: GE Discovery ST System

Regulation Number: 21 CFR 892.1200 Regulation Name: Emission computed

tomography system

Regulation Number: 21 CFR 892.1750 Regulatory Name: Computed tomography

x-ray system

Regulatory Class: II

Product Code: 90 KPS and JAK

Dated: May 4, 2004 Received: May 10, 2004

## Dear Mr. Duersteler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4692
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## **GE** Healthcare

JUN 1 5 2004

KCX+1220

May 4, 2004

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name:

GE Discovery ST System

Establishment Name and Registration Number of Submitter

Name:

General Electric Medical Systems

Registration Number:

2126677

Corresponding Official:

Larry Kroger

General Electric Medical Systems

P.O. Box 414

Milwaukee, WI 53201

**Device Classification** 

Classification Code:

90 KPS

Panel Identification:

Radiology

Classification Name:

Emission Computed Tomography System

(per 21CFR 892.1200)

Common Name:

Nuclear Medicine Imaging system

Classification Class:

Class II Product

Reason for 510(k) Submission

Modification of legally marketed device.

Identification of Legally Marketed Equivalent Devices

GE Discovery LS System

K040172

### **Device Description**

The Discovery ST is an integrated multi-slice Computed Tomography and Positron Emission Tomography scanner. In addition to providing CT and PET stand-alone capabilities, it uses the CT images to correct for non-uniform attenuation of the PET images and it uses integrated CT and PET images to localize emission activity in the patient anatomy. Discovery ST has capabilities for imaging all available PET tracers and CT contrast agents and can provide inherently registered anatomical and functional information via an integrated user interface. It can also be used as a stand-alone head and whole body multislice computed tomography diagnostic imaging system.

## Description of Change or Modification

The Discovery ST CT-PET System is the same system as described in 510(k) K022872 except that the intended use statement has been revised.



## **GE** Healthcare

510(k) Summary of Safety and Effectiveness May 4, 2004 Page 2

## Intended Use of Device

The GE Discovery ST System is intended for head and whole body attenuation corrected Positron Emission Tomography (PET) imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images.

The Discovery ST is to be used by trained health care professionals for imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions. This can assist in the evaluation, diagnosis, staging, restaging, and follow up of lesions, disease and organ function such as (but not limited to) cancer, cardiovascular disease, and brain dysfunction. This device can also assist in radiotherapy planning.

The Discovery ST can also be used as a stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging system.

## Summary of Studies

Discovery LS bench and clinical data demonstrate the ability of Discovery ST to image injected radiopharmaceuticals for the assessment of metabolic (molecular) and physiologic functions of the body and the ability of Discovery ST to use integrated CT and PET images to localize metabolic activity and FDG uptake in the patient anatomy.

Numerous published medical and scientific articles document the use of PET and PET-CT in evaluation of cancer, cardiovascular disease, and brain dysfunction.

## Conclusion

In the opinion of General Electric Medical Systems, the Discovery ST System with the above revised intended use is substantially equivalent in terms of safety and effectiveness to the currently marketed Discovery LS System with the same intended use, 510(k) K040172.



## Indication for STATEMENT OF INTENDED USE

510(k) Number (if known): K04/220
Device Name: GE Discovery ST System
Indications for Use
The GE Discovery ST System is intended for head and whole body attenuation corrected Positron Emission Tomography (PET) imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images.
The Discovery ST is to be used by trained health care professionals for imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions. This can assist in the evaluation, diagnosis, staging, restaging, and follow up of lesions, disease and organ function such as (but not limited to) cancer, cardiovascular disease, and brain dysfunction. This device can also assist in radiotherapy planning.
The Discovery ST can also be used as a stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging system.
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use OR Over-The-Counter Use (Per 21 CFR 801-109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number

## Attachment C-Need-Review Standards and Criteria-6-e Southern Radiology Associates (SRA) Contract

## EXCLUSIVE PROFESSIONAL SERVICES AGREEMENT FOR RADIOLOGY SERVICES

THIS PROFESSIONAL SERVICES AGREEMENT is made and entered into this day of September, 2012, by and between NorthCrest Medical Center, a Tennessee nonprofit corporation, ("Hospital") and Southern Radiology Associates, PLLC, a Tennessee limited liability company, ("SRA").

#### RECITALS

- WHEREAS, Hospital operates a health care facility known as NorthCrest Medical Center, located in Springfield, Tennessee, and including locations in Pleasant View, Tennessee, White House, Tennessee, and Russellville, Kentucky; and
- WHEREAS, Hospital desires to make available to its patients comprehensive radiology and diagnostic services as more particularly described in Exhibit A, attached hereto and incorporated herein by reference ("Services"); and
- WHEREAS, SRA employs certain radiologists who are licensed and trained to supervise technical personnel in the performance of diagnostic radiology procedures and to interpret the results of the diagnostic procedures and to perform the Services; and
- WHEREAS, Hospital now desires to engage SRA as an independent contractor to provide the Services; and
- WHEREAS, SRA desires to provide the Services to Hospital's patients pursuant to the terms and conditions stated below.
- **NOW, THEREFORE**, in consideration of the recitals above, the terms and conditions and mutual agreements set out below, and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the parties agree as follows:

### 1. SRA'S OBLIGATIONS

1.1. Organizational Status. SRA represents and warrants that it is a professional limited liability company, duly organized and validly existing under the laws of the State of Tennessee, and authorized to engage in the profession of medicine in the specialty of radiology in the State of Tennessee.

### SRA's Representatives.

- 1.2.1. As used in this Agreement, the term "SRA's Representatives" shall mean all of SRA's employees, shareholders, partners, subcontractors, and agents providing professional services under this Agreement.
- 1.2.2. This Agreement is entered into for the purpose of securing the Services. It is agreed that the continued provision of such Services under this Agreement is a material obligation of SRA.

60186339.4

1.3. Qualifications. SRA shall not permit any SRA Representative to perform services under this Agreement until he or she has agreed in writing to be bound by all of the provisions of this Agreement by signing a statement in the form of Exhibit B, attached hereto and incorporated herein by reference, acknowledging the effect on the SRA's Representative's medical staff appointment and clinical privileges at Hospital in the event that this Agreement is terminated or in the event that SRA's Representative is no longer associated with SRA. The following qualifications must be satisfied by each of SRA's Representatives as a condition of providing services under this Agreement:

#### Each of SRA's Representative shall at all times:

- 1.3.1. be accepted by Hospital's Chief Executive Officer; said acceptance may be withdrawn by Hospital's Chief Executive Officer in his or her reasonable discretion at any time with written notice to SRA if such action is consistent with the medical staff bylaws of Hospital. If possible, thirty (30) days notice shall be given;
- 1.3.2. keep and maintain a valid license to engage in the practice of radiology in the State of Tennessee and maintain, in good standing, medical staff membership and/or privileges as may be required under the bylaws of Hospital for SRA's Representative to provide the services contemplated by this Agreement;
- 1.3.3, be certified by the AMA/AOA-recognized Board in the specialty of radiology (or eligible for certification by such Board by virtue of having successfully completed all educational and residency requirements required to sit for the Board examination);
- 1,3.4. keep and maintain, in good standing, all usual and customary, unrestricted narcotics and controlled substances numbers and licenses as required by law and Hospital policy;
- 1.3.5. act in a professional manner, and refrain from any action or conduct that is disruptive or harassing, including but not limited to conduct which is sexual in nature, or any other unprofessional conduct that would result in a negative impact on the reputation of Hospital;
- 1.3.6. be a participating provider in the Medicare, Medicaid, and worker's compensation programs, and must, at Hospital's request, subject to Section 1.8, negotiate in good faith with payors to participate in and extend reasonable discounts to any HMO, PPO, or other health benefits plan in which Hospital participates, as applicable to costs for the Services. Any information regarding payment schedules, discounts, and terms shall be kept confidential by both Hospital and SRA; and
- 1.3.7. satisfy the continuing education and regulatory requirements necessary to meet his or her licensure requirements and to maintain certification in radiology.

#### 1.4 Intentionally omitted.

- 1.5. Responsibility for Services. SRA shall assume complete responsibility for the professional operation of the Services and shall provide all professional services which Hospital requires to be provided through the Services, subject to the requirements of Section 6. Any esoteric, unusual, or other procedures which cannot reasonably be performed by SRA shall be sent to an outside provider selected by Hospital, after consultation with SRA.
- Medical Records. SRA's Representatives shall prepare timely, complete, and accurate medical records in accordance with the policies and procedures of Hospital and all professional standards applicable to medical records documentation. All of such records shall be and remain the property of Hospital; SRA and each SRA's Representative shall have access to those records created by the respective SRA's Representative as may be necessary for the continuing care of the patient and as otherwise permitted by law. Each party agrees to comply with all federal and state laws and regulations governing the security and privacy of individually identifiable health information. All records shall be kept in a secure, confidential manner as required by federal and state law, including but not limited to the Standards for Privacy of Individually Identifiable Health Information (the "Privacy Regulation") and the Health Insurance Reform: Security Standards (the "Security Regulation") published by the U.S. Department of Health and Human Services ("HHS"), 45 C.F.R. parts 160, 162 and 164 under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the HITECH Act and Tenn. Code Ann. Section 47-18-2107 as applicable, and not released to any person or entity without Hospital's permission except (a) upon service of a court order or subpoena, (b) with respect to a lawsuit filed against SRA, or (c) as otherwise required by law SRA agrees to notify Hospital immediately of any legal request for records related to this Agreement.
  - 1.6.1. <u>Electronic Medical Records System.</u> SRA agrees to participate in the electronic medical records system of Hospital's choosing and shall cause its records to be included in said system.
- 1.7. Participation in Medical Staff. SRA's Representatives shall participate actively in the affairs of the medical staff, including, without limitation, re-credentialing, serving on committees and discharging such other obligations as may be requested by the medical staff, governing body, or any duly appointed officer or committee thereof, in accordance with Hospital's medical staff bylaws.
- HMO, PPO, and Payor Agreements. SRA agrees that, as requested by Hospital, SRA shall negotiate in good faith for participation by SRA and any SRA's Representative designated by Hospital in such programs and/or networks in which Hospital may participate with health maintenance organizations, preferred provider organizations, other payors, and physician-hospital organizations. Upon request, Hospital agrees to assist SRA in negotiating terms of participation. However, in the event SRA fails to agree to terms of participation after good faith negotiations with such organizations, and, as a result thereof, Hospital is threatened with exclusion or expulsion from the network or program or reduced compensation for its services, to the extent of three percent (3%) of Hospital's then current patient volume, then Hospital may immediately terminate the exclusive provisions of this Agreement and further, at its sole discretion, terminate the Agreement in its entirety pursuant to Section 7 of the Agreement.

- 1.9. Medicare Assignment. SRA and SRA's Representatives must accept assignment of Medicare and Medicaid benefits on all Medicare and Medicaid patients, SRA and SRA's Representatives must immediately notify Hospital if their participation in the Medicare or Medicaid programs is terminated or limited in any way or if an investigation is commenced which might lead to such termination or limitation.
- 1.10. SRA's Employees and Subcontractors. All personnel provided by SRA, including all SRA's Representatives, are not employees or agents of Hospital, and SRA has full responsibility for compensating such personnel, which compensation shall include, as applicable, but not be limited to, all costs of recruitment, wages, vacation pay, sick leave, retirement benefits, social security, workers' compensation, disability insurance, unemployment insurance, severance pay, or employee benefits of any kind. SRA shall be liable and responsible for any act or omission by its agents and employees, including all SRA's Representatives, which cause (or are alleged to have caused) damage or injury to Hospital or to its employees, patients, or visitors.
- 1.11. Records. SRA shall prepare such administrative and business records and reports related to performing the Services in such format and upon such intervals as Hospital shall reasonably require. SRA shall submit complete and accurate time records documenting all time spent in providing services pursuant to this Agreement. Such time records shall be submitted in intervals and on such forms as Hospital may reasonably require. SRA and SRA's Representatives shall furnish any and all information, records, and other documents related to SRA's service hereunder which Hospital may reasonably request in furtherance of its quality assurance, utilization review, risk management, and any other plans and/or programs adopted by Hospital to assess and improve the quality and efficiency of Hospital's services. As reasonably requested, SRA and SRA's Representatives shall participate in one or more of such plans and/or programs.
- 1.12. Authorization. SRA shall assist Hospital in obtaining and maintaining any and all licenses, permits, and other authorization, plus achieving accreditation standards, which are dependent upon, or applicable to, in whole or in part, SRA's services under this Agreement.
- 1.13. Conflict of Interest. SRA shall inform Hospital of any other arrangements which may present a conflict of interest or materially interfere in SRA's performance of its duties under this Agreement. In the event SRA pursues conduct which does, in fact, constitute a conflict of interest or which materially interferes with (or is reasonably anticipated to interfere with) SRA's performance under this Agreement, Hospital may exercise its rights and privileges under Section 7.3 below. "Conflict of interest" or activity which may "materially interfere" or "is reasonably anticipated to interfere" shall mean performing radiology services in any facility in which the members of Contactor own more than five percent (5%) and which functions as a free-standing imaging center, ambulatory surgery center, or clinic that utilizes professional radiologic services and that is in direct competition with the services which are provided by Hospital and which is to be built within the county of Robertson, Tennessee, unless SRA shall have the express written permission of the CEO of Hospital. SRA shall be permitted to perform locum tenens work at a site that is more than fifteen (15) miles from the site of Hospital provided that the provision of such services does not conflict or interfere with the provision of Services pursuant to this Agreement, and provided such work is approved in advance by Hospital.

- 1.14. Use of Hospital In conjunction with the Services provided by SRA, Hospital hereby agrees to make available to SRA the space indicated on Exhibit C attached hereto and incorporated herein at no charge to the SRA. The parties hereby acknowledge that SRA shall not make referrals to Hospital during the term of this Agreement. SRA agrees not to use, or permit any of SRA's Representatives to use, any part of Hospital for any purpose other than the performance of Services and the practice of medicine in accordance with the clinical privileges granted by Hospital. Without limiting the generality of the foregoing, SRA agrees that no part of the premises of Hospital shall be used at any time as an office for private practice and delivery of care for non-Hospital patients. This provision shall not be construed to prohibit SRA from use of teleradiology equipment for non-Hospital patients. Any such use of teleradiology equipment shall require the prior written approval of Hospital and shall be subject to a rental fee. Such equipment is the property of Hospital and shall be returned to Hospital upon termination of the Agreement or upon severance of the relationship between SRA and SRA's Representative in possession of the equipment.
- 1.15. Incurring Obligation. Neither SRA, nor any SRA's Representative, shall have the right or authority to enter into any contract in the name of Hospital or otherwise bind Hospital in any way without the express written consent of Hospital. Neither SRA nor SRA's Representative shall incur any financial obligation on behalf of Hospital without the prior written approval of Hospital. SRA or SRA's Representatives shall be responsible for all personal and professional expenses, including but not limited to liability insurance premiums, membership fees, dues, and expenses of attending conventions and meetings.
- 1.16. <u>Compliance</u>. SRA and SRA's Representatives shall comply with the bylaws, rules and regulations, policies, and directives of Hospital and its medical staff.
- contractor and not as a partner or agent of Hospital. SRA and SRA's Representatives shall not act or hold themselves out to third parties as a partner, employee, joint venturer, or agent of Hospital in the provision of Services. Notwithstanding anything herein to the contrary, Hospital shall not have or exercise such control over the manner in which the medical duties of SRA's Representatives are performed as would jeopardize the status of SRA or SRA's Representatives as independent contractors with Hospital or which would cause Hospital to be treated as violating any legal prohibition against the corporate practice of medicine.
- 1.18. Coverage. The parties acknowledge that prompt and adequate service coverage is of utmost importance to Hospital and its patients. SRA agrees to provide service coverage 24 hours a day, 7 days a week, including weekends and holidays, and to provide the Services on a scheduled and emergency basis. SRA shall employ or contract with sufficient physician personnel which Hospital, in its reasonable discretion, shall deem necessary for the proper operation of the Services. Coverage requirements for the provision of the Services include, but are not limited to, the following:
  - 1.18.1. Scheduled Cases. SRA must work with Hospital to maintain a flexible schedule in order to accommodate the needs of Hospital's patients and medical staff. To the extent possible, Hospital shall provide SRA with advance written notice of its schedule requests.

- 1.18.2 Emergency Cases. SRA must provide on-call coverage for emergencies 24 hours a day, 7 days a week, including weekends and holidays. SRA must be ready to receive images by teleradiology within thirty (30) minutes after first being called.
- 1.18.3. Schedule of SRA's Representatives. SRA must provide Hospital with a monthly schedule, by shift, indicating the name(s) of SRA's Representatives who shall be on duty for the scheduled cases and emergency on-call services. A list of back-up SRA's Representatives who shall be readily available to provide additional coverage should the need arise shall be provided:
- 1.18.4. SRA's Representative Absence. SRA is responsible for making arrangements satisfactory to Hospital, and at no additional cost to Hospital, due to the absence of one or more scheduled SRA's Representatives for any reason.
- 1.19. Radiation Safety Officer ("RSO"). SRA shall provide an RSO who is jointly appointed by Hospital and SRA. RSO shall have such obligations required for RSOs under federal and state law and regulations, accrediting agencies (such as the Joint Commission on the Accreditation of Healthcare Organizations) and other entities affecting service at hospitals and health care entities. In addition, the RSO shall comply with those objectives mutually agreed to by SRA and Hospital. An RSO may be removed by Hospital and a replacement RSO appointed by Hospital and SRA jointly in the event that Hospital, in its sole discretion and in good faith, and for any personal or professional reason, deems that an RSO should be replaced.

#### 2. MEDICAL DIRECTOR

2.1. <u>Medical Director.</u> SRA shall provide one physician practitioner who shall-serve as the medical director ("Medical Director") of the Services. Medical Director shall be selected according to the procedure set forth in Hospital's medical staff bylaws, if there is such a procedure set forth therein; if the medical staff bylaws do not establish a procedure for selecting Medical Director, then the individual selected to serve as Medical Director is subject to Hospital's approval.

Medical Director shall fulfill all duties described in the medical staff bylaws for the director or chief of service in accordance with the highest professional standards. Medical Director shall devote such time as is necessary to provide Services to patients at Hospital and as is necessary to provide consultations to other physicians on the medical staff. Absences, when necessary, must be scheduled in advance with the approval of Hospital and provided that one of the remaining physician practitioners, who is acceptable to Hospital, is designated to serve as acting Medical Director during such absence. Medical Director shall attend at least seventy-five percent (75%) of the required departmental and committee meetings of Hospital's medical staff and shall be represented by another physician practitioner at those meetings he or she is unable to attend. Medical Director may be removed as Medical Director by Hospital in the event Hospital at its sole discretion per any personal or professional reason deems that Medical Director should be removed or exchanged.

- 2.2. <u>Duties.</u> Duties of Medical Director shall include, but not be limited to, the following:
  - 2.2.1. Medical Director must carry out administrative functions for the Services, including but not limited to development of policies and procedures, ongoing review and improvement of operations, and provision of administrative reports and records. Medical Director must develop a program for measuring the quality of care in providing Services and the utilization of Hospital resources against accepted standards of care. Medical Director must actively participate and assist in the investigation and resolution of complaints regarding Services. Medical Director shall assist Hospital in obtaining all necessary permits, licenses, and approvals. Upon request, Medical Director shall serve as Hospital's authorized agent for the purpose of making inquiries to the National Practitioners Data Bank regarding practitioners. Medical Director shall ensure that all practitioners meet the requirements for accreditation or participation established by the JCAHO, Medicare, Medicaid/TennCare, or other regulatory entities as required. Medical Director shall provide such other administrative support as the CEO may reasonably request.
  - 2.2.2. Medical Director shall participate as requested in the administrative functions as necessary to ensure the effective and efficient management of Services.
  - 2.2.3. Medical Director shall participate as requested in Hospital's plans and programs adopted to assess and improve the quality and efficiency of Hospital's services, including but not limited to quality assessment and improvement, utilization review, risk management, and infection control.
  - 2.2.4. Medical Director shall provide such supervision, management, and oversight to the Services to assure that the professional services rendered meet or exceed accepted standards of care.
  - 2.2.5. Medical Director shall participate as requested in the long-range planning of Hospital, including but not limited to equipment selection, budgeting, and staffing
  - 2.2.6. Medical Director shall provide for in-service training for Hospital's employees and SRA's Representatives.
  - 2.2.7. Medical Director shall cooperate with Hospital regarding administrative, operational, or personnel problems in the performance of the Services and promptly inform Hospital and appropriate medical staff committees of professional problems in the performance of the Services in accordance with medical staff bylaws, rules and regulations, and Hospital policy.
  - 2.2.8. Medical Director shall assist Hospital in obtaining and maintaining accreditation and all licenses, permits, and other authorizations, plus achieving all accreditation standards which are dependent upon, or applicable to, in whole or in part, the manner in which the Services are conducted.

- 2.2.9. Medical Director shall ensure the maintenance of accurate, complete, and timely patient and other records regarding the Services in order to facilitate the delivery of quality patient care and provide the information required for Hospital to obtain payment for its services.
- 2.2.10. Medical Director shall review and prepare documentation to ensure compliance with standards/regulations of Tennessee Department of Health, JCAHO, and CMS.
- 2.2.11. In consideration of services performed by Medical Director, Hospital agrees to pay a monthly fee to SRA based upon a rate of \$100 per hour. Medical Director. Medical Director shall spend no more than ten (10) hours per month providing Medical Director services pursuant to this Agreement, and Medical Director shall submit complete and accurate records documenting time spent in providing such services to Hospital's Chief Executive Officer, or his or her designee, within ten (10) business days following each service provided.

# 3. HOSPITAL OBLIGATIONS

- 3.1. Space, Equipment, Supplies, and Services. Hospital shall provide on Hospital premises the space designated by Hospital for the performance of the Services, plus any expendable supplies, equipment, and services necessary for the proper operation of the Services, janitorial, standard hospital telephone, laundry services, and utilities. Hospital agrees to cooperate with SRA in permitting SRA, at its sole cost and expense, to install a dedicated line for support of SRA's separate network, provided such installation shall only be performed under the direct supervision of Hospital's designated representative. After January 1, 2013, Hospital shall provide SRA with five (5) remote teleradiology work stations and associated equipment for its use during the term of this Agreement; as well as any necessary IT support and training services to achieve initial connectivity and compatibility of such work stations with Hospital's systems. Hospital agrees to provide SRA access to Hospital's radiology reading room, the costs and expenses of which shall be solely those of SRA.
- 3.2. <u>Personnel.</u> Hospital shall employ all non-physician technical and clerical personnel necessary for the proper operation of the Services. The Medical Director shall direct and supervise the technical work and services of such department personnel. However, Hospital retains full administrative control and responsibility for all such service personnel, and Hospital shall be liable and responsible for any act or omission by its agents and employees, which cause (or are alleged to have caused) damage or injury to SRA or to its employees or patients.
- 3.3. Billing. Hospital and SRA shall make their own independent charges for services to patients, and each shall independently bill for and collect the charges due to them. However, for their mutual assistance in billing and collecting these charges, they agree that (1) Hospital shall post notices to identify to patients who receive the Services that Hospital and SRA each bill separately; (2) Hospital shall assist SRA in obtaining patient signatures on assignments of benefits; and (3) Hospital shall promptly make its medical records available to SRA for billing by SRA, in accordance with its normal billing practices so as not to delay SRA's billing cycle. Hospital will cooperate in providing billing information in an electronic format when possible.

#### 4. SRA'S REPRESENTATIONS AND WARRANTIES

SRA makes the following representations and warranties to Hospital:

- 4.1. SRA's Representatives Qualifications. SRA warrants that all SRA's Representatives are and shall for the term of this Agreement remain fully qualified as described in Section 1 of this Agreement.
- 4.2. No Violation. SRA is not in breach of, and shall not during the term of this Agreement be in breach of, any other contract, obligation, or covenant that would affect its ability to perform hereunder and, as a result of entering into this Agreement, shall not breach any such contract, obligation, or covenant.
- A.3. Prior Actions. SRA represents and warrants to Hospital that SRA and SRA's Representatives (i) are not currently excluded, debarred, or otherwise ineligible to participate in the Federal health care programs as defined in 42 USC §1320a-7b(f) ("Federal health care programs"); (ii) are not convicted of a criminal offense related to the provision of health care items or services but have not yet been excluded, debarred, or otherwise declared ineligible to participate in the Federal health care programs; and (iii) are not under investigation or otherwise aware of any circumstances which are likely to result in SRA or any of SRA's Representatives being excluded from participation in the Federal health care programs. This shall be an ongoing representation and warranty during the term of this Agreement and SRA shall immediately notify Hospital of any change in the status of the representation and warranty set forth in this section. Any breach of this section shall give Hospital the right to terminate this Agreement immediately for cause.
- 4.4. Nondiscrimination SRA represents and warrants that it is SRA's policy to provide equal opportunity to persons regardless of race, religion, age, gender, disability, or other classification within federal, state, and local statutes, regulations, or ordinances.

## 5. FEES AND BILLING

5.1. SRA Billing. The sole source of compensation under this Agreement to SRA and SRA's Representatives for professional services to patients for the Services will be the fees collected by SRA from its patients or responsible third-party payors. SRA and SRA's Representatives will be responsible at its or their own expense for all such billing and collection. Except as specifically permitted in writing by the CEO or as specifically allowed under Medicare Part B requirements, with respect to Medicare patients SRA and SRA's Representatives will bill and collect only for those professional services that (i) are personally furnished for an individual patient by a SRA's Representative; (ii) contribute directly to the diagnosis or treatment of the patient; (iii) ordinarily require performance by a physician; and (iv) comply with all other requirements contained in the laws and regulations governing payment to physicians under Part B of the Medicare program. With respect to non-Medicare patients, SRA and SRA's Representatives will bill and collect for professional services pursuant to applicable third-party payor rules and guidelines. Hospital agrees to provide SRA with information, within its control, in accordance with the requirements of Section 3.3.

- 5.2. <u>Hospital Billing</u>. Hospital will be responsible for billing patients or third-party payors for services of SRA defined under the Medicare program as constituting "services to the hospital" such as administrative and supervisory services performed by SRA's Representative. Hospital will also be responsible for billing for the use of equipment, supplies, facilities, and Hospital personnel. Neither SRA nor any SRA's Representative will charge patients for any of these services. Hospital is entitled to retain all amounts collected for such services.
- 5.3. Fees for Services to Hospital. Hospital will make no payments to SRA or to any SRA's Representative, except for the Medical Director as herein provided, for Services provided to Hospital as a requirement or condition of appointment under Hospital's medical staff bylaws. Neither Hospital, SRA, nor SRA's Representatives will charge any patient or payor for such services.

## 6. EXCLUSIVITY AND PRIVILEGES

- 6.1. Exclusivity. Hospital shall not grant medical staff privileges to other physicians to practice the Services during the term of this Agreement unless such physicians are employed by or contracting with SRA. Notwithstanding the foregoing, Hospital may also extend appropriate privileges to other physicians to perform services in emergency cases, to provide special consultations, or to provide services in cases for which SRA's Representatives are not qualified or are unable to render the Services. Other appropriately credentialed cardiologists who are members of the medical staff shall also be allowed to perform nuclear cardiology, echocardiography, and cardiac imaging (including calcium screening for coronary artery stenosis). In addition, in the event future modalities or services are added to the Radiology Department, SRA shall be given the opportunity to have it and/or its SRA's Representatives be appropriately credentialed in order to enable it to provide the new Services. In the event Hospital deems it necessary, in accordance with its standard of care, to have other specialties appropriately credentialed it may do so upon prior consultation with SRA.
- 6.2. Resignation of Appointment. The parties acknowledge that preserving the exclusive nature of the Services is vital to its efficient operation and to the delivery of quality patient care. Moreover, the parties acknowledge that enabling Hospital to seek an exclusive arrangement with other physicians practicing the Services upon the termination or expiration of this Agreement is as vital to the efficient operation of the Services and the delivery of quality patient care as is the current exclusivity of SRA's rights under this Agreement. Therefore, if this Agreement expires or is terminated for any reason, SRA and each SRA's Representative shall immediately tender in writing their voluntary resignation of their medical staff appointment and clinical privileges at Hospital. If during the term of this Agreement any SRA's Representative providing Services ceases to be employed by or a contractor with SRA, such SRA's Representative shall immediately tender in writing his or her voluntary resignation of his or her medical staff appointment and clinical privileges at Hospital.
- 6.3. <u>Failure to Resign; Waiver</u>. In the event that SRA or a SRA's Representative is required by this Agreement to voluntarily resign medical staff appointment and clinical privileges and fails to do so, the board of trustees of Hospital shall, upon the request of Hospital's Chief Executive Officer, unilaterally terminate SRA's Representative's medical staff

appointment and clinical privileges without following the procedures set forth in Hospital's medical staff bylaws. In such case, SRA's Representative expressly waives any right to challenge or review such termination, pursuant to the hearing and appeal provisions of the medical staff bylaws or otherwise. In the event that the medical staff bylaws or other relevant documents provide or are amended to provide for a hearing or other procedure inconsistent with the provisions of this section, the provisions of this Agreement control.

6.4. Non-Disciplinary Nature of Termination. The termination of any SRA's Representative's medical staff appointment and clinical privileges under this Section 6 are non-disciplinary in nature. To the extent allowed by law, Hospital shall not report such resignation/termination to the National Practitioner Data Bank or to other regulatory agencies. However, if a report is required by law, Hospital shall report that the termination is due to the requirements of this Agreement and is not disciplinary in nature and agrees to use reasonable efforts to notify SRA of its intent to report.

## 7. TERM AND TERMINATION

- 7.1. Term. This Agreement shall be effective as of the 1st day of February, 2013 (the "Effective Date"), even though it may be finally executed and delivered on a subsequent date. Unless sooner terminated, this Agreement shall expire and be of no further force and effect as of the end of business on the 1st day of February, 2015. Thereafter, this Agreement shall renew automatically for additional successive periods of two (2) years each unless one hundred eighty (180) days before the end of the then current term a party shall notify the other in writing that it has elected not to renew this Agreement.
- Termination with Cause. Upon request by Hospital, SRA shall remove from service under this Agreement any SRA's Representative who (1) is convicted of a crime other than a minor traffic violation, (2) has a guardian or trustee of its person or estate appointed by a court of competent jurisdiction, (3) becomes disabled so as to be unable to perform the duties required by this Agreement, (4) fails to maintain professional liability insurance required by this Agreement, (5) shall have its license(s) and/or privileges required to perform the Services either suspended, revoked, or otherwise limited, (6) fails to maintain eligibility to participate in federal and/or state health care programs, or (7) fails to comply with any of the terms and conditions of this Agreement after being given notice of that failure and a reasonable opportunity to comply. In addition to removing any such SRA's Representative, SRA shall obtain, at its cost and expense, a substitute for the removed SRA's Representative or otherwise demonstrate its capabilities for continued coverage and ability to provide the Service required by this Agreement. A failure by SRA to timely remove any SRA's Representative upon the occurrence of any of the events listed in Items (1) through (7) above shall be deemed a material breach of this Agreement. If such a material breach is precipitated by an occurrence listed in Items (1) through (6) above, Hospital may immediately terminate this Agreement. Termination for any breach precipitated by an occurrence in Item (7) above, shall be subject to Section 7.3 below. Terms and conditions under this Section hereby specifically include any conduct or activity on the part of a SRA's Representative that, in the reasonable, good faith judgment of Hospital's Chief Executive Officer, (i) endangers the safety of any Hospital medical staff member, employee, patient, or business invitee, (ii) constitutes sexual harassment or hostility directed at any employee of Hospital promoting a hostile work environment under Hospital's human

resource policies as if applied to its own employees, or (iii) constitutes outrageous or unprofessional conduct outside any parameters in the medical staff bylaws or common practice in the industry which disrupts or interferes with the orderly operation or administration of Hospital.

- 7.3. Termination upon Breach. Either party may terminate this Agreement at any time in the event the other party engages in an act or omission constituting a material breach of any term or condition of this Agreement. The party electing to terminate this Agreement shall provide the breaching party with not less than sixty (60) days advance written notice specifying the nature of the breach. The breaching party shall then have forty-five (45) days from the date of the notice in which to remedy the breach and conform its conduct to this Agreement. If such corrective action is not taken within the time specified, this Agreement shall terminate at the end of the sixty (60) day period without further notice or demand.
- 7.4. Immediate Termination by Hospital. Hospital may terminate this Agreement immediately upon the following events:
  - 7.4.1. SRA's failure to timely remove any SRA's Representative upon the failure to satisfy the requirements of Sections 1.3 and 4.3; or
  - 7.4.2. SRA's failure to timely remove any SRA's Representative upon the occurrence of any of the events listed in items (1) through (6) of Section 7.2.
- 7.5. Immediate Termination by Either Party. Either party may terminate this Agreement immediately upon the following events:
  - 7.5.1. Upon Hospital's loss of certification as a Medicare provider,
  - 7.5.2. Upon the closure of Hospital; or
  - 7.5.3. Upon either Hospital's or SRA's general assignment for the benefit of creditors, Hospital's or SRA's petition for relief in bankruptcy or under similar laws for the protection of debtors, or upon the initiation of such proceedings against Hospital or SRA if the same are not dismissed within forty-five (45) days of service.
- 7.6. Compliance of Agreement. Hospital shall have the right to periodically audit the Services provided and SRA's compliance with Hospital's policies and procedures and applicable federal and state rules and regulations (collectively referred to as "Hospital Review"). If Hospital Review indicates that changes or modifications to this Agreement should be made, the parties shall enter into good faith negotiations for the purpose of establishing such amendments or modifications as may be appropriate in order to comply with the recommendations of Hospital Review, while preserving the original intent of this Agreement to the greatest extent possible. If, after thirty (30) days of such negotiations, the parties are unable to reach an agreement as to how or whether this Agreement shall continue, then either party may terminate this Agreement upon sixty (60) days prior written notice to the other party.
- 7.7. No Further Rights. Upon any termination of this Agreement, neither party shall have further rights against, or obligations to, the other party except with respect to any

rights or obligations accruing prior to the date and time of termination and any obligations, promises, or agreements which expressly extend beyond the termination, including but not limited to those set out in Sections 3.3, 5.1, 8, 9, 10.9, and 10.11. Neither SRA nor any of SRA's Representatives shall be allowed access to Hospital or to its equipment for the provision of professional radiologic services. SRA and all SRA's Representatives agree to do nothing in the exercise of their Hospital privileges that may interfere with any contract of Hospital with any other individual or entity for the provision of Services.

## 8. NON-COMPETITION RESTRICTIONS

- 8.1. Non-Competition. During the term of this Agreement, SRA and SRA's Representatives shall not provide any radiological services in any hospital, office, diagnostic imaging facility, or any other facility within a ten (10) mile radius of Hospital. Furthermore, for a period of twelve (12) months following the termination of this Agreement, SRA and SRA's Representatives shall not provide any radiological services in any hospital, office, diagnostic imaging facility, or any other facility within ten (10) mile radius of Hospital. The alternative dispute provisions set forth in Section 10.9 shall not limit or restrict the parties with respect to remedies for matters described in this Section for which an injunction, restraining order, writ of mandamus, specific performance, or other equitable relief may be sought by either party.
- 8.2. Non-Solicitation. During the term of this Agreement and any renewal or extension thereof, and for a period of twelve (12) months following the termination of this Agreement, each party covenants and agrees that it shall not directly or indirectly solicit, hire or contract with any person, or with any entity who employs or contracts with any person, who is employed by the other party at the date of termination or was employed by such other party during the last eighteen (18) months of this Agreement.

# 9. INSURANCE AND INDEMNIFICATION

Professional Liability Insurance Coverage. SRA shall keep and maintain professional liability insurance coverage for itself and each of SRA's Representatives with such insurance companies, issued upon such forms, and containing such terms and limitations reasonably acceptable to Hospital. As a minimum, such insurance shall provide coverage in the amount of One Million Dollars (\$1,000,000) per occurrence, Three Million Dollars (\$3,000,000) in the aggregate. Such coverage shall be provided in such a manner and under such terms so as to provide coverage for all occurrences during the term of this Agreement and shall continue throughout the term of this Agreement. In the event SRA is unable to obtain the required insurance for or on behalf of SRA's Representatives, SRA shall require SRA's Representatives to keep and maintain such insurance coverage individually. All such insurance shall be kept and maintained without cost or expense to Hospital. In the event neither SRA nor SRA's Representatives purchase the required coverage, Hospital, in addition to any other rights it may have under the terms of this Agreement or under law, shall be entitled, but not obligated, to purchase such coverage. Hospital shall be entitled to immediate reimbursement from SRA or SRA's Representative for the cost thereof. Hospital may enforce its right of reimbursement through set-off against any sums otherwise payable to SRA or any SRA's Representative who failed to maintain the required coverage. SRA shall provide Hospital with a certificate or certificates of insurance certifying the existence of all coverages required hereunder. SRA and SRA's Representatives shall request its or their insurance carriers to provide Hospital with not less than thirty (30) days prior written notice in the event of a change in the professional liability policies of SRA or SRA's Representatives. SRA or SRA's Representative shall require their insurance carrier to name Hospital as a certificate holder on all certificates of coverage.

- 9.2. Acts and Omissions Coverage. During the term of this Agreement, Hospital shall keep and maintain, at its sole cost and expense, professional and general liability coverage for the acts and omissions of Hospital, its officers, directors, employees, and agents (excluding SRA and SRA's Representatives should it or they be deemed to be agents notwithstanding the contrary intent of the parties except when SRA and/or SRA's Representatives are performing administrative services on behalf of Hospital and are acting in good faith and within the scope of their duties). All such insurance shall be issued upon such forms and in such amounts that are customary in the hospital industry. Hospital shall provide SRA with a certificate or certificates of insurance certifying the existence of all coverages required hereunder (or, if Hospital has adopted a self-insurance program, appropriate evidence thereof). Hospital shall request its insurance carriers to provide SRA with not less than thirty (30) days prior written notice in the event of a change in the professional liability policies of Hospital.
- 9.3. Common Law Rights. Each party specifically reserves any common law right of indemnity and/or contribution which either party may have against the other.
- 9.4. <u>Indemnification.</u> SRA shall indemnify, defend, and hold Hospital, its successors and assigns, harmless from and against any and all claims for occurrences arising out of the operation and performance of this Agreement, including but not limited to, claims for wages, salaries, benefits, taxes, and all other withholdings and charges payable to, or in respect of, SRA's Representatives for services provided under this Agreement; claims for occurrences of errors, omissions and / or professional malpractice by the SRA and / or SRA's Representatives. Hospital shall indemnify, defend, and hold SRA, its successors and assigns, harmless from and against any and all claims for occurrences arising out of Hospital's obligations under this Agreement.

## 10. MISCELLANEOUS PROVISIONS

the written request of the Secretary of Health and Human Services, the Comptroller General, or any of their duly authorized representatives, SRA shall make available those contracts, books, documents, and records necessary to verify the nature and extent of the costs of providing the Services. Such inspection shall be available for up to four (4) years after the rendering of such services. If SRA carries out any of the duties of this Agreement through a subcontract with a value of Ten Thousand and 00/100 Dollars (\$10,000.00) or more over a twelve (12) month period with a related individual or organization, SRA agrees to include this requirement in any such subcontract. This section is included pursuant to and is governed by the requirements of 42 U.S.C. §1395x(v)(1) and the regulations thereto. No attorney-client, accountant-client, or other legal privilege shall be deemed to have been waived by Hospital, SRA, or any SRA's Representative by virtue of this Agreement.

- 10.2. Change of Circumstances. In the event (i) Medicare, Medicaid, any third-party payor, or any federal, state, or local legislative or regulatory authority adopts any law, rule, regulation, policy, procedure, or interpretation thereof which establishes a material change in the method or amount of reimbursement or payment for the services, or if (ii) any or all such payors/authorities impose requirements which require a material change in the manner of either party's operations under this Agreement and/or the costs related thereto, then, upon the request of either party materially affected by any such change in circumstances, the parties shall enter into good faith negotiations for the purpose of establishing such amendments or modifications as may be appropriate in order to accommodate the new requirements and change of circumstances while preserving the original intent of this Agreement to the greatest extent possible. If, after thirty (30) days of such negotiations, the parties are unable to reach an agreement as to how or whether this Agreement shall continue, then either party may terminate this Agreement upon thirty (30) days prior written notice.
- 10.3. Notice. Any notice required or desired to be given in respect to this Agreement shall be deemed to be given upon the earlier of (i) actual delivery to the intended recipient or its agent, or (ii) upon the third business day following deposit in the United States mail, postage prepaid, certified or registered mail, returned receipt requested. Any such notice shall be delivered to the respective addresses set out below, or to such other address as a party shall specify in the manner required by this Section 10.3. The respective addresses are as follows:

If to Hospital:

NorthCrest Medical Center NorthCrest Drive Springfield, TN 37172 Attn: Chief Executive Officer

If to SRA

Southern Radiology Associates, PLLC 9025 Overlook Boulevard Brentwood, TN 37027 Attn: Jim Wade

Copy to:

Chambliss, Bahner & Stophel, P.C. 1000 Tallan Building, Two Union Square Chattanooga, TN 37402 Attn: Mark A. Cunningham

10.4. Entire Agreement. This Agreement contains the entire agreement of the parties hereto and supersedes all prior agreements, contracts, and understandings, whether written or otherwise, between the parties relating to the subject matter hereof. This Agreement

may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

- 10.5. Partial Invalidity. In the event any provision of this Agreement is found to be legally invalid or unenforceable for any reason, the remaining provisions of the Agreement shall remain in full force and effect provided the fundamental rights and obligations remain reasonably unaffected.
- 10.6. Assignment. Because this is a personal service contract, SRA may not assign any of its rights or obligations hereunder without the prior written consent of Hospital. Hospital may assign this Agreement to any successor to all, or substantially all, of Hospital's operating assets or to any affiliate of Hospital. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and permitted assigns.
- 10.7. Independent SRA. SRA and all SRA's Representatives are performing services and duties under this Agreement as independent contractors and not as employees, agents, partners of, or joint ventures with Hospital. Hospital does retain responsibility for the performance of SRA and SRA's Representatives as and to the extent required by law and the accreditation standards applicable to Hospital. Such responsibility, however, is limited to establishing the goals and objectives for the Services and requiring the Services to be rendered in a competent, efficient, and satisfactory manner in accordance with applicable standards and legal requirements. SRA shall be responsible for determining the manner in which the Services are provided and insuring that the Services are rendered in a manner consistent with the goals and objectives referenced in this Agreement.
- 10.8. Regulatory Requirements. The parties expressly acknowledge that it has been and continues to be their intent to comply fully with all federal, state and local laws, rules and regulations, including, without limitation 42 U.S.C. §1320a-7b. It is not a purpose, nor is it a requirement, of this Agreement or any other agreement between parties, to offer or receive any remuneration or benefit of any nature or solicit, require, induce, or encourage the referral of any patient. Neither party shall make or receive any payment that would be prohibited under state or federal law. Therefore, the parties agree and acknowledge that neither this Agreement nor the compensation paid hereunder is based on or takes into account the admission or referral of patients to Hospital, nor is the compensation for Medical Director's services connected in a any way to any such referral. This Agreement has been drafted with the intent of complying with the advice set forth in the OIG Management Advisory Report: "Financial Arrangements between Hospitals and Hospital-Based Physicians," dated January 31, 1991.
- 10.9. Alternate Dispute Resolution. The parties firmly desire to resolve all disputes arising hereunder without resort to litigation in order to protect their respective business reputations and the confidential nature of certain aspects of their relationship. Accordingly, any controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be settled by arbitration administered by the American Health Lawyers Association, and judgment on the award rendered by the arbitrator or arbitrators shall be binding and conclusive on the parties, and shall be kept confidential by the parties to the greatest extent possible. No disclosure of the award shall be made by the parties except as required by the law or as necessary or appropriate to effectuate the terms thereof.

- 10.10. <u>Third-Party Beneficiaries</u>. This Agreement is entered into for the sole benefit of Hospital and SRA. Nothing contained herein or in the parties' course of dealings shall be construed as conferring any third-party beneficiary status on any person or entity not a party to this Agreement, including, without limitation, any SRA's Representative.
- 10.11. Confidentiality. SRA acknowledges and agrees that this Agreement is confidential. Neither SRA nor any of SRA's Representatives shall disclose this Agreement or any terms hereof to any third parties except as may be necessary to obtain advice and counseling from such party's attorneys, accountants, or financial advisors or as may otherwise be required through legal process.
- 10.12. Governing Law. This Agreement shall be governed by the laws of the state of Tennessee.

IN WITNESS WHEREOF, Hospital and SRA have duly executed this Agreement as of the dates set out beneath their respective signatures.

SRA:

HOSPITAL:

SOUTHERN RADIOLOGY ASSOCIATES, PLLC,

A Tennessee professional limited liability company

Ву:

Its: Date:

NORTHCREST MEDICAL CENTER, INC.

A Tennessee nonprofit corporation

By: lts:

Date

18

# EXHIBIT A

# DESCRIPTION OF THE SERVICES

- 1. General diagnostic radiology (supervision and interpretation)
- 2. Diagnostic ultrasound
- 3. CT
- 4. Mammography
- 5. MRI interpretations
- 6. Diagnostic nuclear medicine studies
- 7. Diagnostic neuroradiology
- 8. Diagnostic invasive procedures
- 9. Diagnostic body imaging

## EXHIBIT B

# SRA'S REPRESENTATIVE STATEMENT

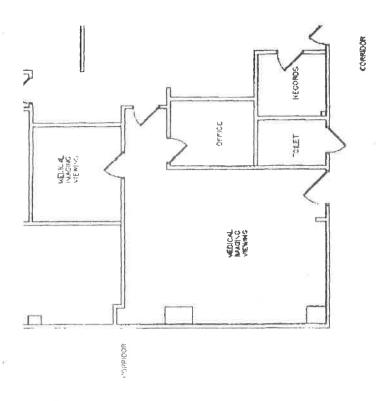
In consideration of my selection to perform the Services as defined in this Agreement, I agree to comply with Hospital's medical staff bylaws in effect from time to time; and I additionally agree to be bound by the terms and conditions concerning the qualifications set forth in Sections 1.3.2, 1.3.3, 1.3.4, 1.3.5, and 1.3.7 of the Agreement, the resignation, disciplinary, and removal provisions in Sections 7.2, items (1) through (6) of the Agreement, the resignation of medical staff appointments and clinical privileges at Hospital, as set forth in Sections 6.2 and 6.3 of the Agreement, and the non-compete and non-solicitation provisions in Section 8 of the Agreement, with the same effect as if I had personally executed such Agreement.

Name:

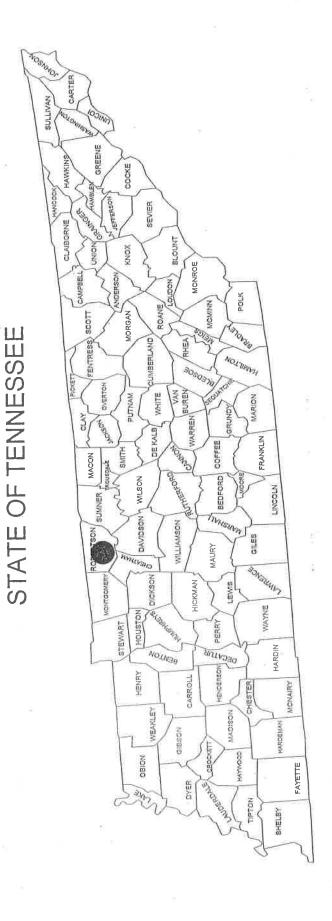
ъ.

Date:

EXHIBIT C
HOSPITAL SPACE FOR USE BY
SRA



# Attachment C-Need-3 Service Area Map



# Attachment C, Economic Feasibility-2-E Financing Letter



April 2, 2015

Ms. Melanie Hill Executive Director Health Services & Development Agency Suite 850 500 Deaderick Street Nashville, Tennessee 37243

Re:

Certificate of Need Application

NorthCrest Medical Center

Dear Ms. Hill:

This letter certifies that NorthCrest Medical Center hereby anticipates funding the above-referenced project in the amount of \$500,000 from cash reserves.

NorthCrest Medical Center's resources are described in the financial data included in the CON application. There are sufficient funds available to fund the above project from current cash reserves.

Sincerely,

Kim Pridgen

Chief Financial Officer

cc: Randy Davis, CEO

Kim H. Looney, Esq. (Waller Lansden)

# Attachment C, Economic Feasibility-10 Income Statement / Balance Sheet Current Audited Financial Statement

# NorthCrest Medical Center Income Statement - YTD Month Ending February 28, 2015

	YTD
Patient Revenue Inpatient Outpatient	43,146,404 116,044,586
Total Patient Revenue	159,190,990
Deduction from Revenue	
Contractual Adj - M/M Contractual Adj - Commercial Contractual Adj - Other Contractual Adj - Charity Care Contractual Adj - Uninsured Disc Bad Debt Expense	56,819,167 46,943,126 873,793 3,514,174 3,782,734 6,373,813
Total Deductions from Rev	118,306,807
Net Patient Revenue	40,884,183
Other Revenue Cafeteria Sales Interest Income Investment Income Contributions Other	173,411 132,235 156,149 315,513 1,136,954
Total Other Revenue	1,914,262
Net Revenue	42,798,445
Operating Expense Salaries Contract Labor Employee Benefits Medical Specialist Fees Contract Services Supplies Maintenance Expense Rental Expense Utilities and Telephones Insurance Taxes Other	15,511,727 1,187,909 4,807,925 422,631 3,056,756 7,367,137 1,496,183 687,613 934,628 420,403 124,361 967,480
Total Operating Expense	36,984,753
EBITDA	5,813,692
Non-Operating Revenue/Expense Depreciation Amortization Unrealized (gain)/loss Interest Mark to Market (gain)/loss Total Non-Operating Exp	2,117,831 851,594 149,421 1,324,954

Net Income

1,369,892

# NORTHCREST MEDICAL CENTER BALANCE SHEET Month Ending February 28, 2015

	actual 2/28/2015
ASSETS	()
Cash and cash equivalents Patient accounts receivable,	16,508,809
net of estimated uncollectibles	13,070,553
Other receivables (net)	370,738
Inventories	1,344,137
Prepaid expenses	710,717
Due from NCPS/Foundation/Strategic Services Estimated receivable under third party program Amounts required for current liabilities-	18,679,342 (550,588)
Assets whose use is limited	0
Total current assets	50,133,708
Assets whose use is limited or restricted: By board for capital improvements	0
Trusteed Funds By donors and grantors for specific purposes	0
Total assets whose use is limited or restricted	0
Other assets	· · · · · · ·
Unamortized bond discount	1,564,388
Unamortized bond issue cost	0
Total other assets	1,564,388
Land, buildings and equipment,net Land and other cost related to future expansion	31,467,044
Total assets	83,165,140
LIABILITIES and FUND BALANCE	
Current liabilities: Current installments under capital leases	4 004 477
Current installments of 2010 Bonds	1,061,477 1,711,500
Accounts payable	2,479,408
Accrued Expenses	1,449,607
Total current liabilities	6,701,992
Long term liabilities: Notes Payable - Long Term	
Capital Leases - Long Term 2010 Bonds - Long Term	1,692,865 40,691,869
Total long term liabilities	42,384,734
Total liabilities	49,086,726
Fund balance: Unrestricted Temporarily restricted by donors and grantors	34,078,414
Total fund balances	34,078,414
Total liabilities and fund balance	83,165,140
. San habilities and faily buildings	00,100,140

# SPRINGFIELD, TENNESSEE

CONSOLIDATED FINANCIAL STATEMENTS

AND
INDEPENDENT AUDITOR'S REPORT

YEARS ENDED JUNE 30, 2014 AND 2013

# $\frac{\text{NORTHCREST MEDICAL CENTER}}{\text{AND AFFILIATES}}$

# SPRINGFIELD, TENNESSEE

# CONSOLIDATED FINANCIAL STATEMENTS AND INDEPENDENT AUDITOR'S REPORT

# YEARS ENDED JUNE 30, 2014 AND 2013

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# INDEPENDENT AUDITOR'S REPORT

To the Board of Trustees NorthCrest Medical Center and Affiliates Springfield, Tennessee

# REPORT ON THE CONSOLIDATED FINANCIAL STATEMENTS

We have audited the accompanying consolidated financial statements of NorthCrest Medical Center and Affiliates (collectively, the "Hospital"), which comprise the consolidated balance sheets as of June 30, 2014 and 2013, and the related consolidated statements of operations and changes in unrestricted net assets, and consolidated statements of cash flows for the years then ended, and the related notes to the consolidated financial statements.

# MANAGEMENT'S RESPONSIBILITY FOR THE CONSOLIDATED FINANCIAL STATEMENTS

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free of material misstatement, whether due to fraud or error.

# AUDITOR'S RESPONSIBILITY

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

# **OPINION**

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of NorthCrest Medical Center and Affiliates as of June 30, 2014 and 2013, and the results of their operations and their cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Nashville, Tennessee October 13, 2014

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# CONSOLIDATED BALANCE SHEETS

# JUNE 30, 2014 AND 2013

	_	2014	_	2013
ASSETS				
Cash and cash equivalents Short-term investments Patient accounts receivable, less allowance for doubtful	\$	3,991,923 4,230,427	\$	2,883,246 6,167,493
accounts of \$6,918,115 in 2014 and \$5,532,288 in 2013		14,304,414		16,374,207
Other receivables		467,351		1,194,363
Current maturities of notes receivable		86,633		32,547
Inventories		1,496,616		1,491,629
Prepaid expenses		760,168		986,831
TOTAL CURRENT ASSETS		25,337,532		29,130,316
Property and equipment, net Loan costs, net of accumulated amortization of \$234,314 in 2014		34,295,618		37,412,793
and \$152,769 in 2013		1,619,520		1,630,957
Notes receivable, less current maturities		341,241		495,534
Investments	-	7,643,365		4,678,412
TOTAL ASSETS	\$	69,237,276	\$	73,348,012
LIABILITIES AND NET ASSETS				
CURRENT LIABILITIES				
Current maturities of long-term debt	\$	1,643,600	\$	2,075,600
Current maturities of capital lease obligations		1,049,820		1,188,889
Accounts payable		1,344,759		1,430,860
Estimated third-party payor settlements Accrued expenses		168,503		622,279
Accrued expenses		4,409,149	-	5,586,520
TOTAL CURRENT LIABILITIES		8,615,831		10,904,148
Fair value of interest rate swap agreement		4,848,069		5,005,282
Long-term debt, less current maturities		37,504,200		39,125,400
Capital lease obligations, less current maturities		2,421,090	_	2,424,753
TOTAL LIABILITIES		53,389,190		57,459,583
Unrestricted net assets		15,848,086	-	15,888,429
TOTAL LIABILITIES AND NET ASSETS	\$	69,237,276	\$	73,348,012

See accompanying notes to consolidated financial statements.

# CONSOLIDATED STATEMENTS OF OPERATIONS AND CHANGES IN UNRESTRICTED NET ASSETS

# YEARS ENDED JUNE 30, 2014 AND 2013

er en	2014	2013	
UNRESTRICTED REVENUES, GAINS AND OTHER SUPPORT Patient service revenue, net of contractual adjustments and discounts Less provision for bad debts	\$ 82,976,533 (12,071,885)	\$ 85,062,732 (11,905,159)	
Net patient service revenue	70,904,648	73,157,573	
Other revenue	2,764,610	3,409,304	
TOTAL UNRESTRICTED REVENUES, GAINS AND OTHER SUPPORT	73,669,258	76,566,877	
EXPENSES Salaries and benefits Supplies and other expenses Purchased services Depreciation and amortization Interest expense	39,432,295 20,685,496 8,084,153 4,575,346 2,096,320	43,416,668 21,706,771 8,304,804 4,160,808 2,144,851	
TOTAL EXPENSES	74,873,610	79,733,902	
OPERATING LOSS	(1,204,352)	(3,167,025)	
NONOPERATING REVENUES Contributions Investment income	371,064 212,478	367,543 705,632	
TOTAL NONOPERATING REVENUES	583,542	1,073,175	
DEFICIENCY OF REVENUES, GAINS AND OTHER SUPPORT OVER EXPENSES	(620,810)	(2,093,850)	
Change in net unrealized gains (losses) on investments Change in fair value of interest rate swap agreement	423,253 157,214	(272,388) 2,208,009	
CHANGE IN UNRESTRICTED NET ASSETS	(40,343)	(158,229)	
NET ASSETS - BEGINNING OF YEAR	15,888,429	16,046,658	
NET ASSETS - END OF YEAR	\$ 15,848,086	\$ 15,888,429	

See accompanying notes to consolidated financial statements.

# CONSOLIDATED STATEMENTS OF CASH FLOWS

# YEARS ENDED JUNE 30, 2014 AND 2013

	_	2014	_	2013
OPERATING ACTIVITIES				
Change in unrestricted net assets	\$	(40,343)	\$	(158,229)
Adjustments to reconcile increase (decrease) in unrestricted net assets to net cash provided by (used in) operating activities:	7	(10,000)	*	(100,227)
Depreciation and amortization		4,692,743		4,305,422
Provision for bad debts		12,071,885		11,905,159
Unrealized (gain) loss on other than trading securities		(423,253)		272,388
Change in fair value of interest rate swap agreement		(157,214)		(2,208,009)
Gain on disposal of property and equipment		(235,897)		(361,725)
Changes in assets and liabilities:				
Patient accounts receivable		(10,002,092)		(14,752,372)
Other receivables		727,012		(952,102)
Inventories		(4,987)		(35,691)
Prepaid expenses		226,663		(254,474)
Accounts payable		(86,101)		73,319
Estimated third-party payor settlements		(453,776)		28,039
Accrued expenses	-	(1,177,371)	-	72,178
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES		5,137,269		(2,066,097)
INVESTING ACTIVITIES				
Purchases of property and equipment		(297,547)		(2,759,286)
Proceeds from sale of property and equipment		312,800		447,711
Purchases of investments		(3,163,753)		(3,499,874)
Proceeds from sale of investments		2,559,119		9,673,911
Advances on notes receivable		(17,190)		(327,435)
Collections on notes receivable			_	4,285
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES		(606,571)	_	3,539,312
FINANCING ACTIVITIES				
Proceeds from issuance of long-term debt		-		492,000
Principal payments on long-term debt		(2,053,200)		(1,373,000)
Principal payments on capital lease obligations		(1,298,713)		(1,066,786)
Payment of loan costs		(70,108)		P.
NET CASH USED IN FINANCING ACTIVITIES		(3,422,021)		(1,947,786)
CHANGE IN CASH AND CASH EQUIVALENTS		1,108,677		(474,571)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR		2,883,246	_	3,357,817
CASH AND CASH EQUIVALENTS - END OF YEAR	\$	3,991,923	\$	2,883,246
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION Cash paid for interest	\$	2,096,320	\$	2,144,851
NONCASH INVESTING AND FINANCIAL ACTIVITIES Assets acquired through capital lease obligations	\$	1,155,979	\$	2,298,351

See accompanying notes to consolidated financial statements,

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 1 - NATURE OF OPERATIONS

NorthCrest Medical Center and Affiliates (the "Hospital") is a Tennessee nonprofit corporation that operates a 109-bed general acute care facility. The Hospital provides a full range of medical services to both inpatients and outpatients in and around the Springfield, Tennessee area.

Admitting physicians are primarily practitioners in the local area.

Also included in the accompanying consolidated financial statements are the Hospital's wholly-owned subsidiaries, NorthCrest Strategic Services, Inc. ("NCSS") and NorthCrest Physician Services, Inc., ("NCPS"), both of which are for-profit corporations engaged in providing healthcare services, NorthCrest Health Network, LLC ("NHN"), a nonprofit physician hospital organization and NorthCrest Medical Center Foundation (the "Foundation" or "NCF"), a Tennessee nonprofit corporation organized to foster, promote, develop and provide healthcare facilities in Robertson County, Tennessee.

# NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

# Basis of Preparation

The accompanying consolidated financial statements have been prepared on the accrual basis in accordance with accounting principles generally accepted in the United States of America.

# Principles of Consolidation

The consolidated financial statements include the accounts of the Hospital, its wholly-owned subsidiaries discussed above and the Foundation. All significant intercompany accounts and transactions have been eliminated in consolidation.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

# Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The most sensitive estimates included in these consolidated financial statements relate to the allowance for doubtful accounts, contractual allowances, estimated third-party payor settlements and self-insurance liabilities. These estimates and assumptions are based on management's best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment. Management adjusts such estimates and assumptions when facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment will be reflected in the consolidated financial statements in future periods.

In particular, laws and regulations governing the Medicare and Medicaid/TennCare programs are extremely complex and subject to interpretation. As a result, there is at least a reasonable possibility that recorded estimates related to these programs will change by a material amount in the near term.

# Cash and Cash Equivalents

Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less when acquired.

# Patient Accounts Receivable and Provision for Bad Debts

Patient accounts receivable are reported net of both an estimated allowance for contractual adjustments and an estimated allowance for uncollectible accounts. The contractual allowance represents the difference between established billing rates and estimated reimbursement from Medicare, TennCare and other third party payer programs. Receivables are generally uncollateralized, but credit risk relating to accounts receivable is limited to some extent by the diversity and number of patients and payors. The Hospital routinely accepts assignment of, or is otherwise entitled to receive, patient benefits payable under health insurance programs, plans or policies. Late fees and interest charges, if any, are recognized when received.

The bad debt allowance is estimated based upon the age of the account, prior experience and any unusual circumstances which affect the collectibility including trends in Federal and state governmental health care coverage and other collection indicators.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

# Investments and Investment Income

Investments consist of U.S. government securities and obligations of its agencies, mortgage-backed securities and marketable equity and debt securities. Investments are measured at fair value.

Short-term investments are stated at cost and consist of money market funds held in brokerage accounts and certificates of deposits with original maturities greater than three months.

Investment income (including realized gains and losses on investments, interest and dividends) is included in nonoperating revenues. Changes in net unrealized gains and losses on investments are excluded from the excess (deficiency) of revenues, gains and other support over expenses.

Investment securities are exposed to various risks such as interest rate, market and credit. Due to the level of risk associated with certain investment securities and the level of uncertainty related to the changes in the fair value of investment securities, it is at least reasonably possible that changes in risks in the near term could materially affect the amounts reported in the accompanying consolidated balance sheets and consolidated statement of operations and changes in unrestricted net assets.

# Notes Receivable

In order to recruit physicians to the Hospital and the surrounding community, the Hospital periodically makes agreements with physicians in which the Hospital guarantees revenue to the physician or pays medical school expenses for the physicians. The Hospital also periodically makes agreements with medical and nursing students to pay education expenses once the students become employees of the Hospital. Each physician or employee signs a note agreement whereby the physician or employee agrees to repay the monies advanced by the Hospital over a certain period of time. However, the note agreements provide that the physician or employee may repay the note by continuing medical practice or employment with the Hospital. In such cases, the Hospital amortizes the related notes over the life of the agreement beginning approximately one year after the physician or employee begins providing medical services. If a physician or employee does not continue providing medical services as required in the note agreement, the physician or employee is required to repay the unamortized portion of the note receivable back to the Hospital.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### Notes Receivable - Continued

The Hospital recognizes interest income when earned. The Hospital's management regularly reviews the notes receivable and provides an allowance for uncollectible amounts when considered necessary. As of June 30, 2014 and 2013, the Hospital did not consider any allowance to be necessary related to the notes receivable.

### Inventories

Inventories, consisting primarily of medical supplies and pharmaceuticals, are stated on the basis of the lower of cost, determined on a first-in, first-out ("FIFO") method or market.

# Property and Equipment

Property and equipment are recorded at cost, or in the case of donated items, on the basis of fair market value at date of donation. Routine maintenance and repairs are charged to expense as incurred. Expenditures that increase values, change capacities or extend useful lives are capitalized, as is interest on amounts borrowed to finance such expenditures.

Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from 10 to 40 years for buildings and 4 to 20 years for equipment. Assets under capital lease obligations are amortized on the straight-line method over the shorter period of the lease term or the estimated useful life of the asset. Amortization of equipment under capital leases is included in the depreciation and amortization on the accompanying financial statements.

## Long-Lived Assets

Management evaluates the recoverability of its investment in long-lived assets on an ongoing basis and recognizes any impairment in the year of determination. It is reasonably possible that relevant conditions could change in the near term and necessitate a change in management's estimate of the recoverability of these assets.

# Loan Costs

Loan costs associated with the issuance of long-term debt are recorded net of accumulated amortization and are amortized using the straight-line method over the term of the respective debt agreements. Amortization expense amounted to approximately \$82,000 and \$79,000 for 2014 and 2013, respectively. Amortization related to loan costs is expected to be approximately \$83,000 for each year ending June 30, 2015 through 2019.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

# Compensated Absences

The Hospital's policy is to compensate employees for unused, earned vacation leave. Accumulated vacation pay is accrued as of the balance sheet date because it is payable upon termination of employment if certain conditions are met. The aforementioned liability is included in accrued expenses and is classified as a current liability in the accompanying consolidated balance sheets.

# Net Assets

All resources that are not restricted by donors are included in unrestricted net assets. Resources temporarily restricted by donors for specific purposes are reported as temporarily restricted net assets. When the specific purposes are achieved, either through passage of a stipulated time or the purpose for restriction is accomplished, they are reclassified to unrestricted net assets and reported in the consolidated statement of operations and changes in net assets. Resources temporarily restricted by donors for additions to land, building and equipment are initially reported as temporarily restricted net assets and are transferred to unrestricted net assets when expended. Donor-imposed restrictions which stipulate that the resources be maintained permanently are reported as permanently restricted net assets. Investment income for these permanently restricted net assets is classified as either temporarily restricted or unrestricted based on the intent of the donor. At June 30, 2014 and 2013, there are no permanently or temporarily restricted net assets.

### Net Patient Service Revenue

Net patient service revenue is reported at estimated net realizable amounts from patients, third-party payors and others for services rendered, including estimated retroactive and prospective adjustments under reimbursement agreements with third-party payors. Third-party payors retain the right to review and propose adjustments to amounts reported by the Hospital. Such adjustments are accrued on an estimated basis in the period the related services are rendered and adjusted in future periods as final settlements are determined.

The primary third-party programs include Medicare and Medicaid/TennCare, which account for a significant amount of the Hospital's revenue. The laws and regulations under which the Medicare and Medicaid/TennCare programs operate are complex and subject to interpretation and frequent changes. As part of operating under these programs, there is a possibility that government authorities may review the Hospital's compliance with these laws and regulations. Such review may result in adjustment to program reimbursement previously received and subject the Hospital to fines and penalties. Although no assurance can be given, management believes it has complied with the requirement of these programs.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### YEARS ENDED JUNE 30, 2014 AND 2013

### NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### Charity Care

The Hospital provides care to patients who meet certain criteria under its charity policy without charge. Because the Hospital does not pursue collection of amounts determined to qualify as charity care, they are not reported as revenue. The Hospital maintains records to identify and monitor the level of charity care they provide. Those records include the amount of charges for services and supplies furnished to patients at no charge.

# Electronic Health Record Incentive Payments

The American Recovery and Reinvestment Act of 2009 began providing for Medicare and Medicaid incentive payments beginning in 2011 for eligible hospitals and professionals that adopt and meaningfully use certified electronic health record ("EHR") technology. The Hospital must attest to certain criteria in order to qualify to receive the incentive payments. The amount of the incentive payments are calculated using predetermined formulas based on available information, primarily related to discharges and patient days. The Hospital utilizes a grant accounting model to recognize EHR incentive revenues and recognizes revenues related to Medicare incentive payments ratably over each EHR reporting period (October 1 to September 30) when it has met meaningful use requirements for certified EHR technology for the EHR reporting period. The Hospital recognized Medicare EHR revenue of \$242,280 and \$855,344 for 2014 and 2013, respectively. The Hospital recognizes Medicaid incentive payments in the period that it qualifies for the funds based on the provisions of the State of Tennessee Division of Medicaid. The Hospital recognized \$178,160 and \$122,733 of revenues related to Medicaid EHR incentive programs for 2014 and 2013, respectively.

The EHR revenues are reflected in other operating revenues on the accompanying consolidated statements of operations and changes in net assets. Future incentive payments could vary due to certain factors such as availability of federal funding for both Medicare and Medicaid incentive payments and the Hospital's ability to implement and demonstrate meaningful use of certified EHR technology. The Hospital has, and will continue to incur both capital costs and operating expenses in order to implement its certified EHR technology and meet meaningful use requirements in the future. These expenses are ongoing and are projected to continue over all stages of implementation of meaningful use. The timing of recognizing the expenses may not correlate with the receipt of the incentive payments and the recognition of revenues. There can be no assurance that the Hospital will demonstrate meaningful use of certified EHR technology in the future, and the failure to do so could have a material, adverse effect on the results of operations. As a part of operating this program, there is a possibility that government authorities may make adjustments to amounts previously recorded by the Hospital. The Hospital's attestation of demonstrating meaningful use is also subject to review by the appropriate government authorities. The amount of revenue recognized is based on management's best estimate, which is subject to change. Such changes will be reflected in the period in which the changes occur.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

### NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

# Excess (Deficiency) of Revenues, Gains and Other Support Over Expenses

The consolidated statements of operations and changes in unrestricted net assets include excess (deficiency) of revenues, gains and other support over expenses. Changes in unrestricted net assets, which are excluded from excess (deficiency) of revenues, gains and other support over expenses, consistent with industry practice, include changes in the net unrealized gains and losses on investments and changes in the fair value of the interest rate swap agreement.

# Operating Activity

The Hospital's primary purpose is to provide healthcare services through its acute care facility. As such, activities related to the ongoing operations of the Hospital are classified as operating revenues. Operating revenues include those generated from direct patient care, related support services, gains or losses from disposition of operating properties and miscellaneous revenues related to the operations of the Hospital. In addition, contributions and earnings on interest-bearing investments that are used to support health-related activities are reported as nonoperating revenue.

### Income Taxes

The Hospital and the Foundation are exempt from federal income taxes under the provisions of Internal Revenue Code Section 501(c)(3), and, accordingly, no provision for income taxes is included in the consolidated financial statements. The Hospital's wholly-owned subsidiaries are for-profit corporations and are taxed under Subchapter "C" of the Internal Revenue Code. These for-profit corporations have incurred significant tax losses. Due to the uncertainty of future taxable income, net deferred tax assets of approximately \$3,420,000 at June 30, 2014 and \$3,020,000 at June 30, 2013 have been fully reserved. The most significant deferred items relate to net operating loss carryforwards, the allowance for doubtful accounts and accrued vacation. These entities have approximately \$14,140,000 of net operating losses available at June 30, 2014 that may be used to offset future taxable income. The net operating losses expire in various years beginning June 30, 2019.

The Hospital follows the guidance for accounting for uncertainty in income taxes recognized in the Hospital's consolidated financial statements that prescribes a recognition threshold of more-likely-than not to be sustained upon examination by the appropriate taxing authority. Measurement of the tax uncertainty occurs if the recognition threshold has been met. The guidance also addresses the derecognition, classification, interest and penalties, accounting in interim periods and required disclosures.

The Hospital has determined that there are no significant uncertain tax positions at June 30, 2014 or 2013. If interest and penalties are incurred related to uncertain tax positions, such amounts would be recognized in income tax expense. Tax periods for all fiscal years after 2010 remain open to examination by the federal and state taxing jurisdictions to which the Hospital is subject.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### Fair Value Measurements

The Hospital classifies its investments based on a hierarchy consisting of: Level 1 (securities valued using quoted prices from active markets for identical assets), Level 2 (securities not traded on an active market but for which observable market inputs are readily available) and Level 3 (securities valued based on significant unobservable inputs).

An asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used maximize the use of observable inputs and minimize the use of unobservable inputs.

The following is a description of the valuation methodologies used for assets measured at fair value on a recurring basis:

Investments - Fair values for investments are determined by reference to quoted market prices and other relevant information generated by market transactions. Fair values for investments in U.S. Treasury securities, debt obligations and mortgage-backed securities are based primarily on other observable values, such as interest rates and yield curves.

No changes in the valuation methodologies have been made since the prior year.

The methods described above may produce a fair value calculation that may not be indicative of net realizable value or reflective of future fair values. Furthermore, while the Hospital believes its valuation methodologies are appropriate and consistent with that of other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in different fair value measurements at the reporting date other observable values, such as interest rates and yield curves.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

# Advertising and Promotion Costs

Advertising and promotion costs are expensed as incurred. Advertising costs for the year ended June 30, 2014 and 2013 were \$308,954 and \$326,589, respectively.

### Reclassifications

Certain reclassifications were made to the prior year's consolidated financial statements to conform to the current year presentation. These reclassifications had no effect on previously reported results of operations or net assets.

# NOTE 3 - CREDIT RISK AND OTHER CONCENTRATIONS

The Hospital generally maintains cash and cash equivalents on deposit at banks in excess of federally insured amounts. The Hospital has not experienced any losses in such accounts.

The Hospital's primary concentration of credit risk is patient accounts receivable, which consist of amounts owed by various governmental agencies, insurance companies and patients. The Hospital manages the receivables by regularly reviewing its accounts and contracts and by providing appropriate allowances for uncollectible amounts. The mix of receivables from patient and third-party payors as of June 30, 2014 and 2013 were as follows:

	2014	2013
Medicare	20 %	21 %
Medicaid/TennCare	14	14
Other third-party payors	34	31
Self-pay	32	34
Total	100	100

Concentration of credit risk relating to accounts receivable is limited to some extent by the diversity and number of patients and third-party payors.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

### NOTE 4 - PATIENT SERVICE REVENUE

The Hospital has agreements with third-party payors that provide for payments to the Hospital at amounts different from its established rates. A summary of the payment arrangements with major third-party payors follows:

### Medicare

Inpatient acute care services rendered to Medicare program beneficiaries are paid at prospectively determined rates per discharge. These rates vary according to a patient classification system that is based on clinical, diagnostic and other factors. The Hospital is reimbursed for these items at a tentative rate with final settlement determined after submission of annual cost reports by the Hospital and audits thereof by the Medicare fiscal intermediary. The Hospital's classification of patients under the Medicare program and the appropriateness of their admission are subject to an independent review by a peer review organization. The Hospital's Medicare cost reports have been audited by the Medicare fiscal intermediary through June 30, 2011.

For outpatient services, the Center for Medicare and Medicaid Services ("CMS") established an outpatient prospective payment system ("OPPS") which established groups called Ambulatory Payment Classifications ("APC") for outpatient procedures. Payment is made for each APC depending upon the service rendered.

# Medicaid

The Medicaid program reimburses the Hospital for the cost of services rendered to Medicaid beneficiaries at a prospective rate which is based on the lower of the reimbursable cost of services rendered or a reimbursement cap set by Medicaid. The reimbursement cap is expressed as a per diem.

Laws and regulations governing the Medicare and Medicaid programs are extremely complex and subject to interpretation. As a result, there is at least a reasonable possibility that recorded estimates could change by a material amount in the near term. For the years ended June 30, 2014 and 2013, net patient service revenue increased approximately \$591,000 and \$38,000, respectively, due to adjustments in excess of amounts previously estimated.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 4 - PATIENT SERVICE REVENUE (CONTINUED)

# TennCare

The TennCare program is a managed care program to provide healthcare coverage to those previously eligible for Medicaid as well as the uninsured population. The Hospital contracts with various managed care organizations which offer both health maintenance organization and preferred provider organization healthcare products. Inpatient reimbursement to the Hospital is received through per diems and Diagnosis-Related Group ("DRG") payments. Outpatient payments are generally received on a discounted fee-for-service basis.

The TennCare program also provides for Essential Access Hospital ("EAH") payments. The methodology for distributing these funds considers each hospital's relative contribution to providing services to TennCare members with eligibility determined each quarter. The Hospital received \$764,813 and \$674,733 for the years ended June 30, 2014 and 2013, respectively. EAH payments are presented as a reduction of contractual adjustments.

### Other

The Hospital has entered into other reimbursement arrangements with certain commercial insurance carriers, health maintenance organizations and preferred provider organizations. The basis for payment to the Hospital under these agreements includes prospectively determined rates per discharge, discounts from established charges and prospectively determined daily rates.

The composition of patient service revenue for the years ended June 30, 2014 and 2013 was as follows:

	2014	2013
Gross patient service revenue Less provisions for contractual and other adjustments		\$ 243,018,989 157,956,257
	\$ 82,976,533	\$ 85,062,732

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 4 - PATIENT SERVICE REVENUE (CONTINUED)

The composition of gross revenues for patient services rendered for the years ended June 30, 2014 and 2013 were as follows:

	2014	3	2013	
Medicare	30	%	32	%
Medicaid/TennCare	19		18	
Other third-party payors	41		39	
Self-pay	10	<i>2</i> -	11	
Total	100	a	100	

## NOTE 5 - CHARITY CARE

The Hospital maintains records to identify and to monitor the level of charity care it provides. These records include the amount of charges forgone for services and supplies furnished under its charity care policy, the estimated cost of those services and supplies and equivalent service statistics. The direct and indirect costs associated with these services cannot be identified to specific charity care patients. Therefore, management estimated the costs of these services by calculating a cost to gross charge ratio and multiplying it by the charges associated with services provided to patients meeting the Hospital's charity care guidelines. Costs incurred for charity, based on the cost to charge ratio, was approximately \$1,668,000 and \$1,675,000 in 2014 and 2013, respectively. Included in gross patient service revenues and other adjustments for 2014 and 2013 are approximately \$5,556,000 and \$5,198,000, respectively, from uncompensated care pools.

### **NOTE 6 - INVESTMENTS**

The composition of investments at June 30 was as follows:

		2014	_	2013
Money market funds	\$	4,230,427	\$	6,167,493
U.S. Treasury securities and obligations of the				
U.S. Government and its agencies		5		507,635
Mortgage-backed securities		366,241		655,454
Equity securities		2,669,850		1,270,978
Corporate bonds	_	4,607,274		2,244,345
Total	\$	11,873,792	\$	10,845,905

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

#### NOTE 7 - NOTES RECEIVABLE

At June 30, 2014 and 2013, the Hospital had \$427,874 and \$528,081, respectively, in unsecured notes receivable due from physicians who practice at the Hospital or in the surrounding community and non-physicians who receive reimbursement for tuition expenses. The notes mature at various dates through December 2018 and bear interest at rates commensurate with market rates at the time of the loan (ranging from 5.0 percent - 9.0 percent).

Amortization related to these notes was \$117,397 and \$144,614 in 2014 and 2013, respectively and included within supplies and other expenses on the consolidated statements of operations and changes in unrestricted net assets. In addition, the Hospital made additional advances under such note agreements of \$17,190 and \$327,435 during 2014 and 2013, respectively.

# NOTE 8 - PROPERTY AND EQUIPMENT

Property and equipment at June 30 was as follows:

		2014	5	2013
Land	\$	4,150,958	\$	4,150,958
Buildings		47,365,127		47,620,490
Equipment		43,502,100	_	42,133,876
		95,018,185		93,905,324
Less accumulated depreciation and amortization	-	(60,722,567)		(56,492,531)
	\$	34,295,618	\$	37,412,793

Depreciation and amortization expense related to these assets was approximately \$4,494,000 and \$4,082,000 in 2014 and 2013, respectively.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### YEARS ENDED JUNE 30, 2014 AND 2013

### NOTE 9 - LONG-TERM DEBT

Long-term debt at June 30 was as follows:

	-	2014	_	2013
Hospital Revenue Refunding Bonds, Series 2010A (a)	\$	26,821,802	\$	27,932,914
Hospital Revenue Refunding Bonds, Series 2010B (a)		5,163,198		5,377,086
Hospital Revenue Refunding Bonds, Series 2010C (a)		2,261,000		2,374,000
Hospital Revenue Refunding Bonds, Series 2010D (a)		4,901,800		5,025,000
Term Loan (b)	-	<u>=</u>	_	492,000
Total long-term debt		39,147,800		41,201,000
Less current maturities		(1,643,600)		(2,075,600)
	\$	37,504,200	\$	39,125,400

(a) Effective December 30, 2010, the Hospital issued The Health and Education Facilities Board of the City of Springfield, Hospital Revenue Refunding Bonds, Series 2010A, 2010B, 2010C and 2010D ("2010 Revenue Bonds") which were primarily used to advance refund the Series 2008 and 2006B Hospital Revenue Refunding Bonds. As a result of the refinancing, the Hospital paid off the bonds and was legally released as the obligor of the Series 2008 Hospital Revenue Refunding Bonds and the Series 2006B Hospital Revenue Bonds.

Interest is payable monthly at variable rates (2.01 and 2.03 percent at June 30, 2014 and 2013 for Series 2010A and 2010B, respectively) (2.70 and 2.74 percent at June 30, 2014 and 2013 for Series 2010C and 2010D, respectively), principal is payable in annual installments through August 2032; collateralized by a first deed of trust on the Hospital building, accounts receivable, inventory, equipment, furniture and fixtures.

The master trust indenture, under which the 2010 Revenue Bonds were issued, and the related reimbursement and credit agreements contain several covenants, the most restrictive of which are the maintenance of certain minimum financial ratios and limitations on the incurrence of additional debt. Effective September 30, 2013, the Financing Agreement was amended to change the required Debt Service Coverage Ratio.

(b) In June 2013, the Hospital entered into a loan agreement for \$492,000 with First Tennessee Bank NA. The interest rate was variable at LIBOR plus 275 basis points per annum. Debt service payments commenced on July 31, 2013 and were payable monthly through June 30, 2014.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 9 - LONG-TERM DEBT (CONTINUED)

A summary of future maturities of long-term debt as of June 30, 2014 were as follows:

Year Ending		
June 30,	-	Amount
2015	\$	1,643,600
2016		1,719,200
2017		1,793,800
2018		1,883,400
2019		1,969,200
Thereafter		30,138,600
	\$	39,147,800

## NOTE 10 - CAPITAL LEASE OBLIGATIONS

The Hospital leases equipment under capital lease agreements that expire at various times and have various renewal options.

The Hospital's obligations under these capital leases as of June 30 were as follows:

	-	2014	-	2013
Minimum lease payments payable	\$	3,654,317	\$	3,797,264
Less portion representing interest		(183,407)		(183,622)
Capital lease obligations		3,470,910		3,613,642
Less current maturities	-	(1,049,820)	3:	(1,188,889)
Long-term maturities	\$	2,421,090	\$	2,424,753

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 10 - CAPITAL LEASE OBLIGATIONS (CONTINUED)

Year Ending

Amortization expense

Future minimum annual lease payments payable under the capital leases as of June 30, 2014 were as follows:

June 30,				
2015 2016 2017 2018 2019 Minimum lease payments payable Less portion representing interest	\$	1,136,883 1,084,322 736,191 565,220 131,701 3,654,317 (183,407)		
	\$	3,470,910		
Equipment utilized under capital leases as of June	30 v	vas as follows	1	
		2014		2013
Equipment Less accumulated depreciation	\$	12,026,638 (8,325,675)	\$	10,864,609 (7,189,185)
	\$	3,700,963	\$	3,675,424

1,136,490 \$

891,807

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

### NOTE 11 - EMPLOYEE BENEFIT PLANS

The Hospital has a defined contribution retirement plan. Employees were eligible to participate in the Plan on the first day of the month following the date the employee completed 90 days of service and had attained the age of 19. Effective January 1, 2013, the Plan was amended making employees eligible to participate in the Plan on the first day of the month following the date the employee completes one year of service and has attained the age of 21. The Hospital makes a matching contribution of 25 percent of employee contributions up to 3 percent of compensation. In addition, the Hospital can make discretionary contributions to the plan as defined in the plan document. The Hospital's retirement plan contribution expense was approximately \$150,500 and (\$228,350) for the years ended June 30, 2014 and 2013, respectively.

During 2011, the Hospital entered into a self-funded health insurance program for its employees. Prior to entering into the self-funded arrangement, the Hospital provided for employee health insurance under a fully insured plan. Claims against the program are administered by an independent risk management firm. Claims are recorded as an expense as they are paid. An annual estimate is accrued for both reported claims and claims incurred but not reported at year end. The Hospital has recorded a reserve in the amount of \$795,000 and \$922,000 at June 30, 2014 and 2013, respectively. Total expense for claims incurred for the year ended June 30, 2014 and 2013 was \$3,202,401 and \$3,866,505, respectively.

Effective January 1, 2013, the Hospital entered into a stop loss insurance policy which may limit claims expense paid for both individual employees and in the aggregate once certain claims thresholds have been exceeded during the policy year. Premiums for the stop loss policy are paid by the Hospital based upon the number of employees per month.

### NOTE 12 - OPERATING LEASES

The Hospital leases various equipment and office space under operating leases expiring at various dates through December 2019. Total rental expense in 2014 and 2013 for all operating leases was approximately \$1,728,000 and \$1,650,000, respectively.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 12 - OPERATING LEASES (CONTINUED)

The following is a schedule by year of future minimum lease payments under noncancelable operating leases as of June 30, 2014, that have initial or remaining lease terms in excess of one year:

Year Ending		
June 30,		
2015	\$	718,955
2016		273,724
2017		71,888
2018		28,385
2019	-	6,711
	\$	1,099,663

It is expected that in the normal course of business, leases and service agreements that expire will be renewed or replaced by other leases; thus, it is anticipated that future lease and service agreement payments will not be less than the commitment for 2015.

### NOTE 13 - COMMITMENTS AND CONTINGENT LIABILITIES

The Hospital currently maintains medical malpractice insurance on a claims-made basis through Arch Specialty Insurance Company ("Arch"). The Hospital's policy with Arch offers coverage for any claims incurred and reported during the policy period. Should the Hospital's claims made medical malpractice policy not be renewed or replaced with equivalent insurance, claims that are reported subsequent to the policy date will not be insured. The Hospital intends to continue carrying the claims-made insurance. Management and legal counsel are not aware of any incidents that would ultimately result in a loss in excess of the Hospital's insurance coverage.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

### NOTE 14 - DERIVATIVE FINANCIAL INSTRUMENT

Effective August 1, 2008, in connection with the issuance of the 2008 Revenue Refunding Bonds, the Hospital entered into an interest rate swap agreement with a financial institution to reduce the impact of changes in interest rates on the bonds. During 2011, the 2008 Revenue Refunding Bonds were paid off. However, the swap agreement was kept in place to hedge the variable interest rates associated with the new debt (see Note 9). The interest rate swap agreement was amended and restated as of November 1, 2011. Under the amended interest rate swap agreement, which is classified as a cash flow hedge, the Hospital pays interest monthly at a fixed rate of 3.56 percent and receives interest monthly at 65% of the one-month LIBOR. The net amounts paid to or received from the counterparty to the swap are included in interest expense. The interest rate swap agreement is recorded at fair value with fair value being determined based upon quoted year-end market rates. Changes in the fair value of the interest rate swap are recorded as a component of unrestricted net assets. The agreement terminates in August 2033 and has an original notional amount of \$38,020,000. Notional amounts do not quantify risk or represent assets or liabilities of the Hospital, but are used in the determination of cash settlements under the agreement.

At June 30, 2014 and 2013, derivative financial instruments consisted of the following:

Designated for hedging:

	2014					
Description	Notional	Maturity	Pay Index	Receive Index	Fair Value	
Fixed payor	\$ 31,985,000	August 2033	3.56%	65% of 1 - month LIBOR	\$ (4,848,069)	
1.		2	2013			
Description	Notional	Maturity	Pay Index	Receive Index	Fair Value	
Fixed payor	\$ 33,310,000	August 2033	3.56%	65% of 1 - month LIBOR	\$ (5,005,282)	

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 15 - FAIR VALUE MEASUREMENTS

The following table sets forth the Hospital's major categories of assets and liabilities measured at fair value on a recurring basis, by level within the fair value hierarchy, as of December 31:

Tan value on a reculting basis,	•					
	Fair Value Measurements at June 30, 2014					
Quoted Prices in Active		Significant Other	Significant	T-4-1 -4		
	Markets for Identical Assets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Total at June 30, 2014		
Financial assets				3		
Mortgage-backed securities Equity securities Corporate bonds	\$ = 2,669,850 4,607,274	\$ 366,241	\$	\$ 366,241 2,669,850 4,607,274		
Total assets	\$ 7,277,124	\$ 366,241	\$ -	\$ 7,643,365		
Financial liabilities Interest rate swap	\$ -	\$ 4,848,069	\$ -	\$ 4,848,069		
Total liabilities	\$ -	\$ 4,848,069	\$ -	\$ 4,848,069		
	Fair	r Value Measurem	ients at June 30, 20	013		
	Quoted Prices	Significant				
	in Active	Other	Significant			
	Markets for Identical Assets	Observable	Unobservable	Total at		
	(Level 1)	Inputs (Level 2)	Inputs (Level 3)	June 30, 2013		
Financial assets						
Government securities	\$	\$ 507,635	\$ -	\$ 507,635		
Mortgage-backed securities		655,454		655,454		
Equity securities	1,270,978		H	1,270,978		
Corporate bonds	2,244,345			2,244,345		
Total assets	\$ 3,515,323	\$ 1,163,089	\$ -	\$ 4,678,412		
Financial liabilities						
Interest rate swap	\$ =	\$ 5,005,282	\$ =	\$ 5,005,282		
Total liabilities	\$ -	\$ 5,005,282	\$ -	\$ 5,005,282		

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## YEARS ENDED JUNE 30, 2014 AND 2013

# NOTE 16 - FUNCTIONAL EXPENSES

The Hospital provides general healthcare services to residents within its geographic location. Expenses related to providing these services are accumulated by function as follows at June 30.

	_	2014	-	2013
Nursing and other professional services	\$	51,466,454	\$	54,612,913
General and administrative office		16,735,490		18,815,330
Depreciation and interest	_	6,671,666	_	6,305,659
	\$	74,873,610	\$	79,733,902

# NOTE 17 - SUBSEQUENT EVENTS

In preparing these consolidated financial statements, the Hospital has evaluated events and transactions for potential recognition or disclosure through October 13, 2014, the date the consolidated financial statements were available to be issued.

In October 2014, the Hospital received payments of approximately \$562,000 related to a class-action settlement for the rural floor neutrality with Medicare cost reports for periods ending 2008 through 2011.

# Attachment C, Contribution to the Orderly Development of Health Care-7(c) Current License / The Joint Commission Accreditation

# Board for Licensing Health Care Facilities



0000000099 No. of Beds 0109

# DEPARTMENT OF HEALTH

3	NORTHCREST MEDICAL CENTER	inai a ucense is necesy graniea	oy the Viate Department of Greatin to  to conduct and maintain a
Hospital		NORTHCREST MEDICAL CENTER	
Cocated at	100 NORTHCREST DRIVE, SP	RINGFIELD	
County of	ROBERTSON	, Tennessee.	
This	license shall expire	JULY 02	
to the provision	ns of Chapter 11, Tennessee		shall not be assignable or transferable, Health, for failure to comply with the
laws of the St	tate of Tennessee or the rules	and regulations of the State D	Department of Health issued thereunder.
In Witness Q	Whereof, we have hereunto set	our hand and seal of the State	this 2ND day of JULY , 2014
In the Distinc	cl talegory (ies) of: PEDIATRIC	HOSPITAL BASIC HOSPITAL	

# NorthCrest Medical Center

Springfield, TN

has been Accredited by



# The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Hospital Accreditation Program

June 8, 2013

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, M.D.

Chair, Board of Commissioners

Organization ID #7910

Print/Reprint Date: 11/4/13

Mark R. Chassin, MD, FACP, MPP, MPH

President

The Joint Commission is an independent, not-for-profit, national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.











# Attachment C, Contribution to the Orderly Development of Health Care-7(d) Licensure / Certification Inspection Report



October 8, 2013

Re: # 7910

CCN: #440065

Program: Hospital Accreditation Expiration Date: June 08, 2016

Scott Raynes CEO NorthCrest Medical Center 100 NorthCrest Drive Springfield, Tennessee 37172

Dear Mr. Raynes:

This letter confirms that your June 04, 2013 - June 07, 2013 unannounced full resurvey was conducted for the purposes of assessing compliance with the Medicare conditions for hospitals through The Joint Commission's deemed status survey process.

Based upon the submission of your evidence of standards compliance on August 13, 2013 and September 25, 2013, The Joint Commission is granting your organization an accreditation decision of Accredited with an effective date of June 08, 2013.

The Joint Commission is also recommending your organization for continued Medicare certification effective June 08, 2013. Please note that the Centers for Medicare and Medicaid Services (CMS) Regional Office (RO) makes the final determination regarding your Medicare participation and the effective date of participation in accordance with the regulations at 42 CFR 489.13. Your organization is encouraged to share a copy of this Medicare recommendation letter with your State Survey Agency.

This recommendation applies to the following location(s):

NorthCrest Medical Center 100 Northcrest Drive, Springfield, TN, 37172

NorthCrest Medical Center d/b/a NorthCrest Endocrinology Center 510 NorthCrest Drive, Springfield, TN, 37172

NorthCrest Medical Center d/b/a NorthCrest Laboratory at NorthCrest Family HealthCare 2102 Park Plaza Drive, Springfield, TN, 37172

NorthCrest Medical Center d/b/a NorthCrest Laboratory at NorthCrest Care Center 520 NorthCrest Drive, Springfield, TN, 37172

www.jointcommussion.org

Headquarters

One Renaissance Boulevard Oakbrook Terrace, IL 60181 630 792 5000 Voice



NorthCrest Medical Center d/b/a NorthCrest Laboratory at The Center for Women's Health 212 NorthCrest Drive, Springfield, TN, 37172

NorthCrest Medical Center d/b/a NorthCrest Laboratory at Pleasant View Family HealthCare 2536 Highway 49, Pleasant View, TN, 37146

NorthCrest Medical Center d/b/a NorthCrest Lab at NorthCrest Medical Care in White House 121 Highway 76, White House, TN, 37188

NorthCrest Medical Center d/b/a NorthCrest Imaging and Specialty Clinic 2536 Highway 49 Ste 120, Pleasant View, TN, 37146

NorthCrest Medical Center d/b/a NorthCrest Imaging at NorthCrest Medical Care in White House 121 Highway 76, White House, TN, 37188

NorthCrest Medical Center d/b/a NorthCrest Imaging at NorthCrest Care Center 520 NorthCrest Drive, Springfield, TN, 37172

We direct your attention to some important Joint Commission policies. First, your Medicare report is publicly accessible as required by the Joint Commission's agreement with the Centers for Medicare and Medicaid Services. Second, Joint Commission policy requires that you inform us of any changes in the name or ownership of your organization, or health care services you provide.

Sincerely,

Mark G. Pelletier, RN, MS

Chief Operating Officer

Division of Accreditation and Certification Operations

cc: CMS/Central Office/Survey & Certification Group/Division of Acute Care Services

CMS/Regional Office 4 /Survey and Certification Staff

# NorthCrest Medical Center Evidence of Standard Compliance 60-day Action Plan August 13, 2013 / September 25, 2013

## HOSPITAL

### Standard:

EC.02.01.01 - EP 5 Indirect - C Partial Compliance The hospital maintains all grounds and equipment.

# Finding:

Multiple isolation room exhausts and the Pathology hood exhausts on the roof were not labeled as hazardous.

## Who:

The Director of Plant Operations is responsible to maintain all grounds and equipment including the proper hazardous labeling of the isolation room and Pathology hood exhausts.

### What:

All isolation room and Pathology hood exhausts have been labeled with the appropriate hazardous exhaust labels.

## When:

All isolation room and Pathology hood exhausts were labeled with the appropriate hazardous exhaust labels on June 7, 2013.

### How:

All isolation room and Pathology hood exhausts will be inspected monthly as part of the monthly Environment of Care rounding to assure continued compliance.

# **Evaluation Method:**

- 1. 100% of the exhausts will be checked on a monthly basis as part of monthly EOC rounding.
- 2. Compliance will be monitored by the Director of Plant Operations and reported to the Environment of Care Committee and Accreditation Coordinator each month for a minimum of four consecutive months.
- 3. The denominator equals the total number of isolation and Pathology hood exhausts
- 4. The numerator equals the total number of exhausts with proper hazardous labels in tact.

# Measure of Success:

The expected measure of success will be greater than 90%.

EC.02.03.05 EP 25 – Indirect - C

Partial Compliance

Documentation of maintenance, testing and inspection activities for fire alarm and water-based fire protection includes the following: name, date, required frequency, name & contact information, including affiliation, of the person who performed the activity, NFPA standard(s) referenced, & results.

# Finding:

The contracted vendors annual and quarterly fire alarm testing / inspection documentation did not include the NFPA standard(s) referenced for the activities performed.

### Who:

The Director of Plant Operations is responsible to assure that documentation of maintenance, testing, and inspection activities for fires alarm and water-based fire protection includes all the required elements outlined in the EC.02.03.05 EP #25 including the NFPA standard(s) referenced.

#### What:

The contracted agency was notified and new reports were completed for the fire alarms systems, as well as the fires suspension systems to include all required elements outlined in the standard including the addition of the NFPA standard(s) referenced.

# When:

Revised fire alarms systems reports including the NFPA standard(s) referenced were completed on June 19, 2013. Revised fire suspension systems reports including the NFPA standard(s) referenced were completed on June 24, 2013.

### How:

The Director of Plant Operations will review each quarterly and annual fire alarm and fire suspension system report to assure that each report contains all required elements outlined in the standards including NFPA standard(s) referenced.

EC.02.05.01 EP 1 – Indirect - A Insufficient Compliance

The hospital designs and installs utility systems that meet patient care and operational needs.

# **Findings:**

Medical gas cylinder storage room in Wound Center stored more than 3000 cubic feet of gas in which there was no dedicated mechanical exhaust or critical electrical systems in place.

# Who:

The Director of Plant Operations is responsible to assure the hospital has dedicated mechanical exhaust or critical electrical systems in place for the storage of more than 3000 cubic feet of gas.

## What:

All medical gas storage areas were checked. Medical gases in excess of 3000 cubic feet of gas per storage room were removed and taken to the oxygen park storage shed located outside the facility.

### When:

All medical gases in excess of 3000 cubic feet per storage room were removed June 12, 2013.

## How:

The Director of Plant Operations will assure compliance with this standard by completing monthly inspections to assure that all medical gas storage areas do not exceed 3000 cubic feet of medical gas.

HR.01.04.01 - EP 7 Indirect - C Partial Compliance

The hospital orients external law enforcement and security personnel on the following: How to interact with patients, procedures for responding to unusual clinical events and incidents, the hospital's channels of clinical, security, and administrative communication, and distinctions between administrative and clinical seclusion.

# Finding:

No evidence of orientation and training of external law enforcement personnel was found to be completed in the Emergency Department.

# Who:

The Director of Inpatient Services is responsible to assure that proper orientation and training of external law enforcement personnel occurs in the Emergency Department.

### What:

The process regarding the orientation of external law enforcement personnel has been revised, sign in logs and orientation material have been updated and approved by Clinical Leadership & the Chief Nursing Officer. Emergency Department staff have been provided education by way of a policy dissemination in Compliance 360, daily Take 5 education, and department staff meetings.

### When:

The policy was reviewed and approved by Clinical Leadership and the Chief Nursing Officer on August 2, 2013. Dissemination and staff meeting education and training regarding the orientation of external law enforcement personnel was completed on August 12, 2013.

### How:

All external law enforcement logs will be forwarded to security. The Director of Plant Operations and Security will review and monitor completion of logs for compliance and notify the Director of Inpatient Services and the Accreditation Coordinator with the results on a monthly basis as a means to assure compliance with this standard.

### **Evaluation Method:**

- 1. 100% of all external law enforcement logs will be reviewed for compliance by the Director of Plant Operation & Security on a monthly basis.
- 2. The Director of Plant Operations & Security will provide a report of staff compliance to the Director of Inpatient Services and the Accreditation Coordinator on a monthly basis.
- 3. The denominator equals the number of law enforcement officers that should have received orientation material
- 4. The numerator equals the number of law enforcement officers that validated they received the orientation material.

# Measure of Success:

The expected measure of success will be greater than 90%.

LD.04.01.01 - EP 2 Indirect - A Insufficient Compliance

The hospital provides care, treatment, and services in accordance with licensure requirements, laws, and rules and regulations.

# **Findings:**

Documentation of the version of the Hepatitis B vaccine sheet was not found in the medical record.

### Who:

The Chief Nursing Officer is responsible to assure that the hospital provides care, treatment, and services in accordance with licensure requirements, laws, and rules and regulations including assuring that the version of the Hepatitis B vaccine sheet provided to the patient is documented in the medical record.

### What:

Documentation of the version of the Hepatitis B vaccine sheet has been added to the electronic medication administration record (MAR). Education has been completed with all Nursery & Women's Services staff at staff meetings to ensure compliance with documentation of the version of Hepatitis B vaccine on the electronic MAR.

### When:

Education regarding documentation of the version of Hepatitis B vaccine on the electronic MAR was completed with Nursery and Women's Services staff on June 7, 2013.

# How:

The Director of Women's Services will complete random medical record reviews to assure ongoing compliance with documentation of the version of Hepatitis B vaccine on the electronic MAR.

LS.02.01.35 - EP 5 Indirect - A Insufficient Compliance Sprinkler heads are not damaged and are free from corrosion, foreign materials, and paint.

# Finding:

Thick layers of dust were found on multiple fire suppression heads (sprinkler heads)

### Who:

The Director of Plant Operations is responsible to assure the fire suppression heads (sprinkler heads) are free of dust.

### What:

All fire suppression heads have been inspected and cleaned. All fire suppression heads have been set up on a routine cleaning and maintenance schedule. Inspections of fire suppression heads have been added to the quarterly EOC rounding schedule.

## When:

All fire suppression heads were inspected and cleaned on June 12, 2013, as well as set up on a routine cleaning and maintenance schedule and added to the quarterly EOC rounding schedule beginning July 1, 2013.

### How:

Inspections of fire suppression heads have been added to the quarterly EOC rounding schedule as a means to validate ongoing compliance with this standard.

LS.02.01.35 - EP 14 Indirect - A Partial Compliance

The hospital meets all other Life Safety Code automatic extinguishing requirements related to NFPA 101-2000: 18/19.3.5

# Finding:

Ceiling tiles were found missing in the Cardiac Rehab storage room. The escutcheon ring was missing from a fire suppression head in the MI waiting room.

### Who:

The Director of Plant Operations is responsible to assure all Life Safety Code automatic extinguishing requirements related to NFPA 101-2000: 18/19.3.5 are met including proper placement of ceiling tiles and fire suppression equipment are in tact.

### What:

All ceiling tiles and fire suppression heads have been inspected and replaced / repaired. Inspections of ceiling tiles (including those in storage areas) and fire suppression heads will be conducted quarterly as part of the EOC rounding schedule.

### When:

All ceiling tiles and fire suppression heads were inspected and replaced or repaired on June 6, 2013, as well as were added to the quarterly EOC rounding schedule starting June 12, 2013.

### How:

Inspections of ceiling tiles (including those in storage areas) and fire suppression heads have been added to the quarterly EOC rounding schedule as a means to validate ongoing compliance with this standard.

MS.08.01.01 - EP 1 Indirect - AC Insufficient Compliance A period of focused professional practice evaluation is implemented for all initially requested privileges.

# Finding:

The policy & process of FPPE was not privilege specific.

## Who:

The Chief Executive Officer is responsible to assure that the period of focused professional practice evaluation implemented for all initially requested privileges provides sufficient evidence of specific privilege experience and competence.

## What:

The FPPE policy and process has been revised and approved by the Chief of Staff and Chief Executive Office to include a review of privilege specific criteria as part of the FPPE evaluation of process.

### When:

Revisions to the FPPE policy and process were reviewed and approved by the Chief of Staff and Chief Executive Officer on August 12, 2013.

### How:

The Medical Staff Coordinator and Chief of Staff will review FPPE files as part of quarterly FPPE process to assure compliance with new policy and process changes.

MS.08.01.03 - EP 1 Indirect - A Insufficient Compliance

The process for the ongoing professional practice evaluation includes the following: There is a clearly defined process in place that facilitates the evaluation of each practitioner's professional practice.

Finding:

The policy and process regarding OPPE Evaluation included that data was reported to department chiefs quarterly, but the data only addressed physicians that trended out. As a result the majority of physician evaluations by department chiefs only occurred at two year reappointments.

### Who:

The Chief Executive Officer is responsible to assure there is a clearly defined process for ongoing professional practice evaluation including evaluation of all physicians on a regular basis.

### What:

The policy and processes involved in OPPE has been revised and approved by the Chief of Staff and Chief Executive Officer to clearly define the data which will be collected on an ongoing basis for each credentialed physician. This data will be reported to and reviewed by the appropriate department chief a minimum of every six months.

### When:

Revisions to the OPPE policy and process were reviewed and approved by the Chief of Staff and Chief Executive Officer on August 12, 2013.

### How:

The Medical Staff Coordinator and Chief of Staff will review OPPE files as part of bi-annual OPPE process to assure compliance with new OPPE policy and process changes.

MS.08.01.03 - EP 3 Indirect - A Insufficient Compliance

The process for the ongoing professional practice evaluation includes the following: Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke existing privileges.

# Finding:

The policy for OPPE did not provide for the evaluation of all practitioners on a frequency that was ongoing (less than every 12 months). Data was reported quarterly but the data only addressed physicians that trended out and the only documentation of decisions by department chiefs occurred at two year reappointments.

### Who:

The Chief Executive Officer is responsible to assure the OPPE process is a clearly defined to determine whether to continue, limit, or revoke existing physician privileges.

### What:

The policy and processes involved in OPPE has been revised to clearly define the data which will be collected on an ongoing basis for each credentialed physician. This data will be reported to and reviewed by the appropriate department chief a minimum of every six months.

### When:

Revisions to the OPPE policy and process were reviewed and approved by the Chief of Staff and Chief Executive Officer on August 12, 2013.

### How:

The Medical Staff Coordinator and Chief of Staff will review OPPE files as part of bi-annual OPPE process to assure compliance with new policy and process changes:

MS.11.01.01 - EP 1 Indirect - A Insufficient Compliance

Process design addresses the following issues: Education of licensed independent practitioners and other organization staff about illness and impairment recognition issues specific to licensed independent practitioners (at-risk criteria).

# Finding:

The organization did not provide evidence of education of the licensed practitioners about illness and impairment recognition issues specific to licensed independent practitioners.

# Who:

The Chief Executive Officer is responsible to assure that all licensed independent practitioners are educated about illness and impairment recognition issues.

### What:

Education provided on medical center policy and processes for recognition, reporting, and treatment of the impaired physician was completed by the Chief of Staff during Department Medical Staff meetings. Additional in-service training provided by the Tennessee Medical Foundation is scheduled for the August Medical Staff meeting. Ongoing education and training has also been added to the every two year re-credentialing process requirements.

### When:

Education provided to all medical staff regarding the medical center policy and processes for recognition, reporting, and treatment of the impaired physician was completed by the Chief of Staff during July Department Medical Staff meetings, as well as in the August physician newsletter disseminated on August 12, 2013. Additional in-service training provided by the Tennessee Medical Foundation is scheduled for the (and was completed on) August 19, 2013 Medical Staff meeting.

### How:

The Medical Staff Coordinator will maintain and monitor documentation of attendance inservice education and training in each licensed independent practitioners credentialing files, and to be included as part of their every two years re-credentialing requirements to assure ongoing compliance with this standard.

PC.01.02.03 - EP 5 Indirect - C Insufficient Compliance

For a medical history and physical examination that was completed within 30 days prior to registration or inpatient admission, an update documenting any changes in the patient's condition is completed within 24 hours after registration or inpatient admission, but prior to surgery or a procedure requiring anesthesia services.

# Finding:

Documentation of the update to the history and physical did not indicate the H&P had been reviewed.

# Who:

The Chief Nursing Officer is responsible to assure that the medical record contains complete documentation including the H&P and updates to be completed within 24 hours after registration or inpatient admission, but prior to surgery or a procedure requiring anesthesia.

### What:

Education has been completed with Medical Staff by the Chief of Staff during July department medical staff meetings as well as in an August newsletter to the physicians.

### When:

Education was completed with all Medical Staff by the Chief of Staff during July 2013 department medical staff meetings, as well as via an August physician newsletter disseminated on August 12, 2013.

### How:

Health Information Management staff will complete monthly chart audits to assess for ongoing compliance.

### Evaluation Method:

- 1. Sample size: Based on our average daily census of 41, 30 medical records will be randomly selected each month.
- 2. An electronic list of all medical records will be generated each month. From this list, every 10th medical record will be pulled until a total of 30 medical records are selected each month.
- 3. The numerator will be the number of compliant updates to the H&P
- 4. The denominator will be the number of opportunities reviewed
- 5. Data will be collected monthly for a minimum of four consecutive months.
- 6. Monthly results will be reviewed by the Director of Health Information Management and reported to the Accreditation Coordinator, Chief Nursing Officer, and Chief of Medical Staff.

### Measure of Success:

The expected measure of success will be greater than 90%.

RC.01.01.01 - EP 11 Indirect - C All entries in the medical record are dated.

Insufficient Compliance

## Finding:

Multiple forms, consents, and physician entries were not dated.

#### Who:

The Chief Nursing Officer is responsible to assure that all medical record entries are dated.

#### What:

All protocols, forms, and consents have been revised to include identified lines for documenting time, date, and authenticating signatures. Education has been provided to all clinical staff in all inpatient and outpatient areas including ED, CCU, OR/SDS, MS2, MS3, WS, MI, CVL, & CP, via staff meetings, email reminders, and daily Take 5 education. All medical staff have also been reminded of documentation requirements via department medical staff meetings and an August physician newsletter disseminated on August 12, 2013.

Results of audits and any needed follow-up action plans developed with organization leaders as a means to improve compliance will be disseminated to all clinical and medical staff via their department Take 5 education, staff meetings, the bi-monthly Clinical Newsletter, as well as medical department staff meetings.

## When:

Revisions of protocols, forms, and consents were completed on August 6, 2013. Clinical staff education was completed on July 10, 2013. Education was completed with Medical Staff by the Chief of Staff by July department medical staff meetings, as well as via an August physician newsletter disseminated on August 12, 2013.

#### How:

Health Information Management staff will complete monthly chart audits to assess ongoing compliance.

RC.01.01.01 - EP 19 Indirect - C
All entries in the medical record are timed.

Insufficient Compliance

## Finding:

Multiple forms, consents, and physician entries were not timed.

#### Who:

The Chief Nursing Officer is responsible to assure that all medical record entries are timed.

#### What:

All protocols, forms, and consents have been revised to include identified lines for documenting time, date, and authenticating signatures. Education has been provided to all clinical staff in all inpatient and outpatient areas including ED, CCU, OR/SDS, MS2, MS3, WS, MI, CVL, & CP, via staff meetings, email reminders, and daily Take 5 education. All medical staff have also been reminded of documentation requirements via department medical staff meetings and an August physician newsletter completed on August 12, 2013.

Results of audits and any needed follow-up action plans developed with organization leaders as a means to improve compliance will be disseminated to all clinical and medical staff via their department Take 5 education, staff meetings, the bi-monthly Clinical Newsletter, as well as medical department staff meetings.

## When:

Revisions of protocols, forms, and consents were completed on August 6, 2013. Clinical staff education was completed on July 10, 2013. Education was completed with Medical Staff by the Chief of Staff by July department medical staff meetings, as well as via an August physician newsletter disseminated on August 12, 2013.

#### How:

Health Information Management staff will complete monthly chart audits to assess ongoing compliance.

RC.01.02.01 - EP 3 Indirect - C Partial Compliance
The author of each medical record entity is identified in the medical record.

## Finding:

Orders were not authenticated in more than one medical record (including a pre-anesthesia assessment & a physician order for a radiology procedure with moderate sedation)

#### Who:

The Chief Nursing Officer is responsible to assure that all medical record entries are authenticated.

#### What:

All protocols, forms, and consents have been revised to include identified lines for documenting time, date, and authenticating signatures. Education has been provided to all clinical staff in all inpatient and outpatient areas including ED, CCU, OR/SDS, MS2, MS3, WS, MI, CVL, & CP, via staff meetings, email reminders, and daily Take 5 education. All medical staff have also been re-educated on documentation requirements via department medical staff meetings and an August physician newsletter.

#### When:

Revisions of protocols, forms, and consents were completed on August 6, 2013. Clinical staff education was completed on July 10, 2013. Education was completed with Medical Staff by the Chief of Staff at July department medical staff meetings, as well as via an August physician newsletter.

#### How:

Health Information Management staff will complete monthly chart audits to assess ongoing compliance.

# Evaluation Method:

- 1. Sample size: Based on our average daily census of 41, 30 medical records will be randomly selected each month.
- 2. An electronic list of all medical records will be generated each month. From this list, every 10<sup>th</sup> medical record will be pulled until a total of 30 medical records are selected each month.
- 3. The percentage of compliance will be measured by dividing the number of times the orders were authenticated (numerator) by the number of total orders that should have been authenticated (denominator).
- 4. Data will be collected monthly for a minimum of four consecutive months.
- 5. Monthly results will be reviewed by the Director of Health Information Management and reported to the Accreditation Coordinator, Chief Nursing Officer, and Chief of Medical Staff.

## Measure of Success:

RI.01.03.01 - EP 13 Indirect - C Insufficient Compliance Informed consent is obtained in accordance with the hospital's policy and processes and, except in emergencies, prior to surgery.

# Finding:

Multiple consents for procedures were not signed by the physician.

#### Who:

The Chief Nursing Officer is responsible to assure that all consents for procedures are signed by the ordering physician in accordance with the hospital's policy and processes.

#### What:

All medical staff have also been re-educated on requirements for signing all consents prior to the procedure via department medical staff meetings and a physician newsletter.

#### When:

Education was completed with Medical Staff by the Chief of Staff at July department medical staff meetings, as well as via an August physician newsletter.

#### How:

Health Information Management staff will complete monthly chart audits to assess ongoing compliance.

#### Evaluation Method:

- 1. Sample size: Based on our average daily census of 41, 30 medical records will be randomly selected each month.
- 2. An electronic list of all medical records will be generated each month. From this list, every 10<sup>th</sup> medical record will be pulled until a total of 30 medical records are selected each month.
- 3. The percentage of compliance will be measured by dividing the number of times the consents were signed by the ordering physician (numerator) by the number of consents that should have been signed (denominator).
- 4. Data will be collected monthly for a minimum of four consecutive months.
- 5. Monthly results will be reviewed by the Director of Health Information Management and reported to the Accreditation Coordinator, Chief Nursing Officer, and Chief of Medical Staff.

#### Measure of Success:

#### HOSPICE

## Standard:

LD.04.03.09 - EP 16 Indirect - A Insufficient Compliance
The Hospice retains management responsibility for the contracted services and verifies that they are furnished in a safe and effective manner.

## Findings:

An opened comfort pack was found containing a syringe labeled ABHR with an expiration date of 2012, while the expiration date on the outside of the pack indicated the expiration date was 8/3/2013.

#### Who:

The Director of Hospice is responsible to assure that contracted services are furnished in a safe and effective manner including assuring the recognition and prompt removal of any expired medications, as well as notification of the contracted service regarding in discrepancies.

#### What:

A meeting was held with the contracted pharmacy responsible for the contents and labeling of comfort packs to clarify processes for external labeling and dating to assure medications are not expired. In-service education was provided by the contracted pharmacy to all Hospice staff regarding the labeling changes and use of the comfort packs, as well as the process to complete patient teaching.

#### When:

The meeting with the contracted pharmacy occurred on June 26, 2013. Staff education was completed on July 9, 2013, as part of the Hospice Quality Assurance and Performance Improvement meeting.

#### How:

Hospice nurses are monitoring the integrity and external packaging expiration dates of patient comfort packs at each visit, as well as whenever a comfort pack is opened for use, as a means to assure compliance with this standard.

MM.05.01.11 - EP 2 Indirect - C Partial Compliance

The organization dispenses medications and maintains records in accordance with law and regulation, licensure, and professional standards of practice.

## Findings:

The medical record indicated morphine was wasted following the death of the patient however, upon visiting another patient and unopened vial of morphine was found in the comfort pack with the first patient's name partially marked out.

#### Who:

The Director of Hospice is responsible to assure that the organization dispense medications and maintains records in accordance with law and regulation, licensure, and professional standards of practice including assuring the integrity of the comfort packs, as well as the proper procedure for reconciling and wasting medications.

#### What:

In-service education was provided by the contracted pharmacy and the Director of Hospice to all Hospice staff regarding the importance of maintaining the integrity of the comfort packs, as well as proper procedure for reconciling and wasting medications.

## When:

Staff education was completed with all Hospice staff on July 9, 2013, as part of the Hospice Quality Assurance and Performance Improvement meeting.

#### How:

The Director of Hospice is assuring compliance through medical record audits.

## Evaluation Method:

- 1. Sample size: 100% of Hospice records will be reviewed for compliance
- 2. The percentage of compliance will be measured by dividing the number of times medication reconciliation and wasting was properly documented (numerator) by the total number of times medication reconciliation and waste should have been completed (denominator).
- 3. Data will be collected monthly for a minimum of four consecutive months.
- 4. Results will be reviewed by the Director of Hospice and reported to the Accreditation Coordinator and Chief Nursing Officer on a monthly basis.

MM.05.01.19 - EP 11 Indirect - A Insufficient Compliance At the time when controlled medications are first ordered, authorized staff document in the patient's record that the written policies and procedures for managing controlled medications were provided and discussed.

Findings:

Documentation regarding the review of policies and procedures for managing and discarding controlled medications with the patient &/or family was not found in multiple medical records.

## Who:

The Director of Hospice is responsible to assure patients &/or their families receive education regarding the organization processes for managing and discarding controlled medications.

#### What:

A new check-off system has been added to the admission process to assure proper documentation of teaching as well as medication waste. In-service education was provided to all Hospice staff regarding the importance of providing patient &/or family education regarding processes for managing and discarding of controlled medications.

#### When:

Staff education was completed with all Hospice staff on July 9, 2013, as part of the Hospice Quality Assurance and Performance Improvement meeting. The new check-off system documentation went into effect on July 10, 2013.

#### How:

The Hospice Nursing supervisor will complete monthly chart audits to assess ongoing compliance.

PC.01.03.01 - EP 41 Indirect - A Insufficient Compliance For Hospice care provided to a resident of a Skilled Nursing Facility (SNF), Nursing Facility (NF), or Intermediate Care Facility for the mentally retarded (ICR/MR), the hospice plan of care reflects the participation of the hospice, the SNF, NF, or ICF/MR, and the patient and family to the extent possible.

# Findings:

The plan of care did not reflect the participation of the nursing facility.

#### Who:

The Director of Hospice is responsible to assure participation of the nursing facility in the development and implementation of the Hospice plan of care.

#### What:

A Hospice representative will attend the nursing facilities interdisciplinary meetings to assure communication and participation of the nursing facility in the development and implementation of the Hospice patient's plan of care. A copy of the facility plan of care will become a part of the Hospice clinical record.

#### When:

Staff education was completed with all Hospice staff on July 9, 2013, as part of the Hospice Quality Assurance and Performance Improvement meeting. Participation in interdisciplinary meetings in facilities where Hospice patients are current residents started July 10, 2013 in accordance with facility schedules.

## How:

The Hospice Nursing supervisor will validate staff attendance at meetings, as well as complete monthly chart audits to assess ongoing compliance.

RC.01.02.01 - EP 9 Indirect - A Insufficient Compliance

All entries in the patient records are legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.

Finding:

Multiple medication orders did not contain the route of administration. Multiple pulse oximetry readings as outlined in the plan of care were not documented in the medical record. A POST form was not completely filled out by the physician as outlined in policy.

#### Who:

The Director of Hospice is responsible to assure all entries in the medical record are legible, clear, complete, and appropriately authenticated and dated.

#### What:

All Hospice medical staff and nurses have been re-educated on requirements for completing the entire POST form, as well as all elements required for medication orders including the prescribed route. Changes to the electronic documentation tool were made to include a mandatory fill in the nursing pathway for the pulse oximetry readings. All Hospice staff were educated on documenting pulse oximetry readings in the electronic record.

## When:

Revisions to the electronic documentation record were made by the software company on July 1, 2013. Education to Hospice physicians were sent via email and as part of the Hospice Quality Assurance and Performance Improvement meeting held on July 9, 2013.

## How:

The Director of Hospice will monitor for compliance by completing medical record audits.

#### Measure of Success:

REMOVED BEFORE FILED - NOT REQUIRED

# NorthCrest Medical Center Evidence of Standard Compliance 45-day Action Plan July 29, 2013 / August 12, 2013

#### HOSPITAL

#### Standard:

EC.04.01.01 - EP 15 Direct - A Insufficient Compliance

The hospital collects information to monitor conditions in the environment. Every 12 months, the hospital evaluates each environment of care management plan, including a review of the plan's objectives, scope, performance, and effectiveness.

# Finding:

There was no evidence that the scope and effectiveness of the environment of care management plans were reviewed.

#### Who:

The chair of the Environment of Care committee (the Chief Nursing Officer) is responsible to oversee the revision of each Environment of Care Management Plan to assure the scope, objectives, performance and effectiveness evaluation criteria are clearly defined.

#### What:

Each Environment of Care Management Plan, including the Life Safety Plan – EOC.1268, Utilities Management Plan – EOC.1338, Security Plan – EOC.1298, Safety Plan – EOC.1319, and Hazardous Materials Plan – EOC.1256, were reviewed and revised to include a more clearly defined scope, objectives, as well as performance and effectiveness evaluation criteria. In addition, the structure of the Environment of Care meeting has been revised to meet the performance effectiveness reporting criteria outlined in the revised plans.

## When:

Structure and changes in reporting processes involved in the Environment Care meetings and revisions to the Environment of Care Management Plans were reviewed as part of the July 25, 2013 Environment of Care meeting and approved by the Chief Nursing Officer on July 29, 2013.

## How:

The processes outlined in the revised Environment of Care Management Plans will be used as the foundation of the monthly Environment of Care meetings as a means to assure performance and effectiveness of each plan. Review and approval of the Environment of Care Plans will be completed annually to assure ongoing compliance.

IC.02.02.01 EP 2 – Direct - A Insufficient Compliance

The hospital implements infection prevention and control activities when doing the following: performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies

# Finding:

A double packaged sterile gomko instrument was found with the inner sealed pouch folded to fit into the outer pouch.

#### Who:

The Director of Outpatient Services is responsible to assure the proper intermediate and high-level disinfection and sterilization of medical equipment, devices and supplies including proper packaging and processing procedures.

#### What:

All intermediate and high-level sterilized equipment, devices, and supplies have been checked to assure product integrity and proper packaging. Central Sterile staff were educated on proper sterile packaging and processing procedures in department staff meetings. Clinical staff were educated in department staff meetings and through daily Take 5's to return all improperly packaged or processed equipment, devices, or supplies.

## When:

All intermediate and high-level sterilized equipment, devices, and supplies in all clinical areas were checked to assure proper packaging on June 5, 2013. Central Sterile staff education on proper packaging and processing procedures was completed via department staff meetings and daily Take 5 communication on June 7, 2013.

## How:

Department staff will check for improperly packaged equipment, devices, and supplies by way of monthly rounding to assure compliance with proper packaging and processing procedures. The surgery coordinator will also supervise random observations as a means to validate processing procedure compliance.

IC.02.02.01 EP 4 – Indirect - C

Partial Compliance

The hospital implements infection prevention and control activities when storing medical equipment, devices, and supplies.

# **Findings:**

Multiple expired supplies including hemocult cards, gen probes, and angiocaths on WS and strep/flu swabs in the pediatric exam room

#### Who:

The Chief Nursing Officer is responsible to assure proper infection prevention and control activities are in place when storing medical equipment, devices and supplies.

#### What:

All clinical areas have been checked and any expired supplies have been removed. Materials Management has reviewed and revised current practice with suppliers to avoid receiving supplies (when possible) with expiration dates of less than six months. Clinical and Materials Management staff have worked together to develop and implement a process of labeling storage bins, drawers, and cabinets with approaching expiration dates, as well as revised their process for restocking and rotating supplies. Supply PAR levels in each area have been reevaluated and adjusted to avoid prolonged storage issues. Return bins have been placed in all clinical areas for staff to return unused supplies that cannot be re-credited to the patient. Staff education on new processes was completed with Materials Management staff, as well as clinical areas including MS2, MS3, CCU, OR/SDS, WS and ED by way of staff meetings and through daily Take 5 communication.

#### When:

Department staff completed a search of all clinical areas for any expired supplies on June 7, 2013. The Director of Materials Management notified suppliers via email, as well as educated Materials Management staff in department staff meeting, that supplies with expiration dates of less than six months would be avoided if at all possible, on June 10, 2013. Revised labeling, restocking and rotating supply processes were fully implemented July 3, 2013. Changes in PAR levels, installation of return bins and staff education via department staff meetings and daily Take 5 communication was completed by July 21, 2013.

#### How:

Materials Management staff will perform monthly rounding, checking the expiration dates of supplies in all clinical areas.

#### **Evaluation Method:**

- 1. Based on our average daily census of 41, 30 items will be selected using random selection
- 2. Each month, every 3rd item on the department inventory sheet of each clinical area including MS2, MS3, CCU, WS, ED, & SDS will be selected. Of those, the first 5 from each area will selected for a total of 30 items to be monitored for the first month and rotating to the next 5 items each month thereafter.
- 3. The denominator equals the total PAR level for each of the 30 items selected each month
- 4. The numerator equals the total number of items found expired each month.
- 5. Data will be collected and presented by the Director of Materials Management to the Accreditation Coordinator, as well as Clinical Leadership on a monthly basis for a minimum of 4 consecutive months.

#### Measure of Success:

LS.02.01.10 - EP 1 Direct - A Insufficient Compliance

Building and fire protection features are designed and maintained to minimize the effects of fire, smoke, and heat.

# Finding:

Structural steel spray coating was missing in multiple areas to accommodate clamps &/or pipes located in the Penthouse Mechanical area & the Physical Plant.

# Who:

The Director of Plant Operations is responsible to assure the building and fire protection features are designed and maintained to minimize the effects of fire, smoke, and heat.

#### What:

Reapplication and re-inspection of structural steel spray coating was completed.

## When:

Reapplication and re-inspection of structural steel spray coating was completed on June 21, 2013.

## How:

The re-inspection of fire prevention structural spray coating will be completed as part of annual Environment of Care inspections, as well as when any potential disruption could occur, such as replacement of clamps and/or work on surrounding pipes.

MM.03.01.01 - EP 7 Direct - C Partial Compliance

All stored medication and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.

## **Findings:**

Isovue contrast found in warmer in the Pleasant View CT imaging area was not labeled with expiration date, rather it was labeled with the date it was place in the warmer and a liter bag of IV fluids found on MS3 removed from over-wrap was not labeled with an expiration date

#### Who:

The Chief Nursing Officer is responsible to assure that all stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.

#### What:

The contrast warmer at the Pleasant View CT Imaging area was removed, as it is no longer required that contrast be stored in a warmer. Because contrast will no longer be stored in warmers they do not have to be labeled with a warmed contrast expiration date. Medical Imaging staff were reminded that contrast is no longer stored in warmers via interdepartmental communication and staff meetings.

All areas and Pyxis cabinets were checked to assure no additional IV fluids were found removed from the over-wrap without a written expiration date. Staff were also educated via staff meetings, daily Take 5 communication, email notification, and laminated reminders to discard all unused large volume IV fluids removed from their protective over-wrap.

#### When:

The contrast warmer was removed and staff educated regarding the proper storage and labeling of contrast on June 5, 2013.

All areas and Pyxis cabinets were checked to assure proper labeling of expiration dates on June 5, 2013 and staff education was completed on July 12, 2013.

#### How:

Pharmacy staff will assess for compliance as part of daily medication rounding process.

## **Evaluation Method:**

- 1. 100% of large volume bags will be monitored by pharmacy staff as part of the daily rounding process.
- 2. The Director of Pharmacy will provide the data to the Accreditation Coordinator and Clinical Leadership on a monthly basis for a minimum of four consecutive months.
- 3. The denominator equals the total number of IVF bags stocked in each inpatient care areas including MS2, MS3, CCU, & WS.
- 4. The numerator equals the total number of IVF bags found removed from the outer packaging without the proper expiration date labeling.

## Measure of Success:

MM.03.01.03 - EP 2 Direct - A Insufficient Compliance Emergency medications and their associated supplies are readily accessible in patient care areas

Finding:

Medication & supplies in emergency reaction kit at Pleasant View CT area were expired as well as supplies in the intubation box located in the Medical Imaging CT area

#### Who:

The Chief Nursing Officer is responsible to assure medications and their associated supplies are readily accessible in patient care areas.

#### What:

The reaction kit found in the Pleasant View CT area was immediately removed, as the use of this kit is not the current practice of this area. The Medical Imaging staff at the Pleasant View Clinic CT area were re-educated on the proper procedure to follow.

All emergency boxes, carts, and kits have been inspected by supervising staff to assure all medications and supplies are current. All emergency boxes, carts, and kits have been labeled with the most current expiration date as a means to alert staff to approaching expiration dates when daily checks are completed. Cardiopulomonary's process for opening and checking intubation box supplies has been revised to be completed on the same bi-monthly schedule as other emergency boxes, kits and crash carts, as outlined in the Code Blue policy. Supervising staff and leaders responsible for checking boxes, carts, and kits have been educated on the process via staff meetings and email communication.

#### When:

The emergency reaction kit found in the Pleasant View CT area was removed on June 6, 2013 and staff education on proper emergency procedures was completed on June 7, 2013.

All emergency boxes, carts, and kits were inspected to assure no expired supplies or medications were present on June 6, 2013. All emergency boxes, carts, and kits were labeled with the most current expiration date as a means to alert staff to approaching expiration dates on June 6, 2013. Cardiopulmonary's process change and education with supervising staff and leaders responsible to checking boxes, carts, and kits was completed June 26, 2013.

#### How:

The Pleasant View CT area has been added to monthly Environment of Care rounding.

Supervising staff and leaders will assess and log compliance as part of bi-monthly checks of emergency boxes, carts, and kits. Any trends will be reported to the Code Committee.

PC.01.02.07 - EP 3 Direct - C Partial Compliance
The hospital reassesses and responds to the patient's pain, based on its reassessment

## Finding:

No documentation of pain assessment prior to and/or after the administration of pain medication was found in two separate medical records

## Who:

The Director of Inpatient Services is responsible to assure the patient's pain is assessed and reassessed in accordance with hospital policy and procedure.

#### What:

Alscripts electronic documentation system was revised to provide prompts and mandatory fields to document pain assessment and reassessment. Staff was re-educated regarding pain assessment/reassessment documentation in Alscripts via completion of HealthStream Education, as well as in daily Take 5, email reminders, and department staff meetings.

## When:

Revisions to the electronic medical record were completed on June 21, 2013. Nursing staff were assigned, and required to complete, a HealthStream Education module on proper documentation of pain assessment and reassessment in Alscripts by July 26, 2013. Additional staff education is ongoing via email reminders, department staff meetings, and daily Take 5 communication.

#### How:

Chart audits will be completed as part of the Quality Departments monthly QA and reporting process to assure pain assessments and reassessments are completed and documented as required in the medical record.

## **Evaluation Method:**

An audit of 5 randomly selected medical records will be reviewed each week from each inpatient area including CCU, MS2, MS3, and WS, totaling 80 charts each month. Medical records will be selected using an average length of stay between three to seven days. Additionally, no medical records will be used more than once. The numerator will equal the number of times pain assessment / reassessment was documented and the denominator will be the number of times pain assessment / reassessment should have been documented. Data will be reported on a monthly basis to the Accreditation Coordinator, as well as the Quality Committee and Clinical Leadership. Data to validate compliance with this standard will be collected beginning August 1, 2013 and continue for a minimum of 4 months.

## Measure of Success:

PC.02.01.11 - EP 2 Direct - A Insufficient Compliance Resuscitation equipment is available for use based on the needs of the population served.

Finding:

An AED was found in locked cabinet in the Pleasant View CT imaging area with expired defibrillator pads

## Who:

The Chief Nursing Officer is responsible to assure all resuscitation equipment is available for use based on the needs of the population served.

#### What:

The AED was removed from the Pleasant View CT imaging area as the use of an AED is not the current practice of this area. The Medical Imaging staff at the Pleasant View Clinic CT area were re-educated on the proper procedure to follow in the event of a cardiac or respiratory arrest.

## When:

The AED found in the Pleasant View CT area was removed on June 6, 2013 and staff education on proper emergency procedures was completed on June 7, 2013.

#### How:

The Pleasant View CT area has been added to monthly Environment of Care rounding at which time staff will be questioned regarding their proper emergency procedures.

PC.03.01.03 - EP 1 Direct - A Insufficient Compliance

Before operative or other high-risk procedures are initiated, or before moderate or deep sedation or anesthesia is administered: The hospital conducts a pre-sedation or pre-anesthesia patient assessment.

# Finding:

The pre-anesthesia evaluation was not complete on multiple medical records, as well as no documentation of the ASA physical status was found prior to moderate sedation in multiple medical records

## Who:

The Chief Nursing Officer is responsible to assure that before operative or other high-risk procedures are initiated, or before moderate or deep sedation or anesthesia is administered a presedation or pre-anesthesia patient assessment is completed.

#### What:

Changes to the ASA documentation tool was completed to assure the actual ASA score has been completed and documented prior to start of the administration of sedation. Medical Staff were reeducated on required pre-anesthesia and moderate sedation documentation. In-service education was completed with nursing staff to assure all required documentation is present prior to the start of any surgical or moderate sedation procedures.

#### When:

The ASA documentation tool was revised and approved by the Chief Nursing Officer on July 19, 2013, and documentation requirements were communicated to medical staff per Chief of Medical Staff on June 14th Medical Executive Committee and further disseminated to medical staff by MS Department chairs completed on July 8, 2013. In-service education via HealthStream e-learning was completed with nursing staff July 25, 2013.

#### How:

Health Information Management will monitor compliance as part of scheduled medical chart reviews. Random audits will also be conducted by the Accreditation Coordinator to assure continued compliance.

PC.03.01.05 - EP 1 Direct - A Insufficient Compliance

The hospital monitors the patient during operative or other high-risk procedures and/or during the administration of moderate or deep sedation or anesthesia. Monitoring includes continuous monitoring of the patient's oxygenation, ventilation, and circulation

## Finding:

No documentation to support the monitoring of the patient's level of consciousness, vital signs, and ETCO2 every 5 minutes during moderate sedation as required by policy

#### Who:

The Chief Nursing Officer is responsible to assure that the patient is monitored during operative or other high-risk procedures and/or during the administration of moderate or deep sedation or anesthesia. Monitoring includes continuous monitoring of the patient's oxygenation, ventilation, and circulation.

#### What:

Inservice education regarding the Moderate Sedation policy - PC.136, clarifying the difference between minimal and moderate sedation, as well as the elements of required monitoring was completed with nursing staff responsible for managing and/or monitoring moderate sedation including Registered Nurses in CCU, ED, CVL, and OR/SDS, as well as nursing supervisors. The medical staff was also provided re-education on all elements of the moderate sedation policy including clarification regarding the difference between minimal and moderate sedation and the elements required for continuous monitoring.

#### When:

Policy clarifications regarding the elements and timing of continuous monitoring of patients receiving moderate sedation were completed and the policy PC.136 was approved by the Chief Nursing Officer on July 19, 2013. Nursing in-service education was completed July 25, 2013.

#### How:

Random audits will be conducted by the department coordinators to assure continued compliance.

PC.04.01.05 - EP 8 Direct - C

Partial Compliance

The hospital provides written discharge instructions in a manner that the patient and/or the patient's family or caregiver can understand

Finding:

No discharge instructions were provided in the Emergency Department to multiple patients/families regarding sedation (Ketamine) administered

## Who:

The Chief Nursing Officer is responsible to assure that discharge instructions are provided to the patient/family/caregiver in a way they can understand.

## What:

The patient education material was developed and loaded into the Emergency Department Alscripts electronic documentation system, which will prompt the nurse to print and give to all patients, family, or caregiver of patients receiving Ketamine.

## When:

The patient education material was developed, loaded into the Emergency Department Alscripts electronic documentation system, and as of June 19, 2013 is being provided to all patients, family, or caregivers of patients receiving Ketamine.

## How:

Chart audits will be completed in the Emergency Department to monitor compliance. Data will be reported to the Director of Outpatient Services, Clinical Leadership, as well as the Accreditation Coordinator.

# **Evaluation Method:**

- 1. All medical records of patients receiving Ketamine in the Emergency Department will be reviewed for compliance.
- 2. The measure of success will be measured by dividing the number of medical records with documentation that Ketamine education was provided (Numerator), by the total number of times Ketamine was given (denominator).
- 3. Data will be collected monthly for a minimum of four consecutive months.
- 4. Monthly results will be reported to the Director of Outpatient Services, Clinical Leadership, as well as the Accreditation Coordinator.

#### Measure of Success:

UP.01.03.01 - EP 5 Direct - C Partial Compliance

A time-out is performed before the procedure

## Finding:

No documentation of the time of the "time-out" for a nerve block & a sciatic nerve block was found in PACU

## Who:

The Director of Outpatient Services is responsible to assure that all time-outs are performed and documented prior to the start of any procedure including nerve blocks.

#### What:

All medical staff have been re-educated of the need to document all time-outs via medical staff meetings. Future plans include the revision of the anesthesia form as a means to provide uniformity of documentation of time-outs.

#### When:

The Medical Chief of Staff completed education at the Medical Executive Committee on June 14, 2013. Each MS department chief completed education on proper documentation of time-outs on the current forms at each department medical staff meeting by July 8, 2013. Implementation of a revised anesthesia form is awaiting approval by the Pharmacy & Therapeutics Committee scheduled on August 27, 2013.

#### How:

An audit of medical records of patients treated in the OR/PACU will be reviewed for compliance with documentation of time outs.

#### **Evaluation Method:**

- 1. An electronic list of all OR/PACU patients will be generated each month. From this list, every 14th medical record will be highlighted until a total of 30 medical records are selected each month.
- 2. The percentage of compliance will be measured by dividing the number of times the time out was documented (numerator) by the number of times it should have been documented (denominator).
- 3. Data will be collected monthly for a minimum of four consecutive months.
- 4. Monthly results will be reported to the Director of Outpatient Services, Clinical Leadership, as well as the Accreditation Coordinator.

## Measure of Success:

### HOSPICE

#### Standard:

PC.02.01.01 - EP 1 Direct - C Partial Compliance

The organization provides care, treatment, or services for each patient according to his/her individualized plan of care

# Findings:

Specific orders for wound dressing changes did not match the care provided.

#### Who:

The Director of Hospice is responsible to assure that care and services are provided in accordance with the plan of care.

#### What:

A new wound care log to identify patients receiving wound care orders has been developed and implemented. Staff has been educated on the new wound care log and the need to follow the physician's order and plan of care.

#### When:

Staff education was completed on July 9, 2013, as part of the Hospice Quality Assurance and Performance Improvement meeting. Implementation of the new wound care log began July 10, 2013.

#### How:

Monthly chart audits of wound care logs and the patient's plan of care will be completed to monitor compliance.

#### **Evaluation Method:**

- 1. 100% of Hospice medical records will be audited each month for a minimum of four consecutive months.
- 2. The denominator equals the number of dressing changes
- 3. The numerator equals the number of dressing changes that followed the physician's order and the plan of care.
- 4. Results will be reviewed by the Director of Hospice and reported to the Chief Nursing Officer and Accreditation Coordinator on a monthly basis.

#### Measure of Success:



# NorthCrest Medical Center 100 NorthCrest Drive Springfield, TN 37172

Organization Identification Number: 7910

Program(s) Hospital Accreditation Home Care Accreditation Survey Date(s) 06/04/2013-06/07/2013

#### **Executive Summary**

Hospital Accreditation: As a result of the accreditation activity conducted on the above date(s), Requirements

for Improvement have been identified in your report.

You will have follow-up in the area(s) indicated below:

Evidence of Standards Compliance (ESC)

**Home Care** Accreditation: As a result of the accreditation activity conducted on the above date(s), Requirements for Improvement have been identified in your report.

You will have follow-up in the area(s) indicated below:

Evidence of Standards Compliance (ESC)

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

# The Joint Commission Summary of Findings

Evidence of DIRECT Impact Standards Compliance is due within 45 days from the day the survey report was originally posted to your organization's extranet site:

Program:	Hospital Accreditation Program		
Standards:	EC.04.01.01	EP15	
	IC.02.02.01	EP2,EP4	-
	LS.02.01.10	EP1	
	MM.03.01.01	EP7	-
	MM.03.01.03	EP2	
	PC.01.02.07	EP3	
	PC.02.01.11	EP2	
	PC.03.01.03	EP1	
r e	PC.03.01.05	EP1	
	PC.04.01.05	EP8	
	UP.01.03.01	EP5	
Program:	Home Care Accreditation Program		
Standards:	PC.02.01.01	EP1	

Evidence of INDIRECT Impact Standards Compliance is due within 60 days from the day the survey report was originally posted to your organization's extranet site:

Program:	Hospital Accreditation Program	
Standards:	EC.02.01.01	EP5
	EC.02.03.05	EP25
	EC.02.05.01	EP1
	HR.01.04.01	EP7
	LD.04.01.01	EP2
	LS.02.01.35	EP5,EP14
	MS.08.01.01	EP1
	MS.08.01.03	EP1,EP3
	MS.11.01.01	EP1
	PC.01.02.03	EP5
	RC.01.01.01	EP11,EP19

# The Joint Commission Summary of Findings

Evidence of INDIRECT Impact Standards Compliance is due within 60 days from the day the survey report was originally posted to your organization's extranet site:

	RC.01.02.01	EP3
	RI.01.03.01	EP13
Program:	Home Care Accreditation Program	
Standards:	LD.04.03.09	EP16
	MM.05.01.11	EP2
	MM.05.01.19	EP11
	PC.01.03.01	EP41
	RC.01.02.01	EP9

# The Joint Commission Summary of CMS Findings

CoP:

§418.100

Tag: L649

**Deficiency:** Standard

Corresponds to: OME

Text:

The hospice must organize, manage, and administer its resources to provide the hospice care and services to patients, caregivers and families necessary for the palliation and management of the terminal illness and related conditions.

CoP Standard	Tag	Corresponds to	Deficiency
§418.100(e)	L655	OME - LD.04.03.09/EP16	Standard

CoP:

§418.106

Tag: L687

Deficiency: Standard

Corresponds to: OME

Text:

Medical supplies and appliances, as described in §410.36 of this chapter; durable medical equipment, as described in §410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.

CoP Standard	Tag	Corresponds to	Deficiency
§418.106(e)(2) (i)(C)	L697	OME - MM.05.01.19/EP11	Standard

CoP:

§482.22

Tag: A-0338

Deficiency: Standard

Corresponds to: HAP

Text:

§482.22 Condition of Participation: Medical staff

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

CoP Standard	Tag	Corresponds to	Deficiency
§482.22(a)(1)	A-0340	HAP - MS.08.01.03/EP1, EP3	Standard

CoP:

§482.24

Tag: A-0431

Deficiency: Standard

Corresponds to: HAP

Text:

§482.24 Condition of Participation: Medical Record Services

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

CoP Standard	Tag	Corresponds to	Deficiency
§482.24(c)(4)(v)	A-0466	HAP - RI.01.03.01/EP13	Standard
§482.24(c)(1)	A-0450	HAP - RC.01.02.01/EP3, RC.01.01.01/EP11, EP19	Standard
§482.24(c)(2)	A-0450	HAP - RC.01.02.01/EP3	Standard
§482.24(c)(4)(i) (B)	A-0461	HAP - PC.01.02.03/EP5	Standard

# The Joint Commission **Summary of CMS Findings**

CoP:

Text:

§482.41

**Tag:** A-0700

**Deficiency:** Standard

Corresponds to: HAP

§482.41 Condition of Participation: Physical Environment

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

CoP Standard	Tag	Corresponds to	Deficiency
§482.41(c)(2)	A-0724	HAP - EC.02.01.01/EP5	Standard
§482.41(a)	A-0701	HAP - EC.04.01.01/EP15	Standard
§482.41(b)(1)(i)		HAP - EC.02.03.05/EP25, LS.02.01.10/EP1, LS.02.01.35/EP5, EP14	Standard

CoP:

§482.42

Tag: A-0747

**Deficiency:** Standard

Corresponds to: HAP - IC.02.02.01/EP4

Text:

§482.42 Condition of Participation: Infection Control

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

CoP:

§482.51

Tag: A-0940

**Deficiency:** Standard

Corresponds to: HAP - IC.02.02.01/EP2

Text:

§482.51 Condition of Participation: Surgical Services

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of

services offered.

CoP:

§418.56

Tag: L538

Deficiency: Standard

Corresponds to: OME

Text:

The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the

terminal illness and related conditions.

CoP Standard	Tag	Corresponds to	Deficiency
§418.56(e)(2)	L555	OME - PC.02.01.01/EP1	Standard

CoP:

§418.104

Organization Identification Number: 7910

Tag: L670

**Deficiency:** Standard

Corresponds to: OME

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# The Joint Commission Summary of CMS Findings

Text:

§418.104 Condition of participation: Clinical records.

CoP Standard	Tag	Corresponds to	Deficiency
§418.104(b)	L679	OME - RC.01.02.01/EP9	Standard

CoP:

Text:

§418.112

**Tag:** L760

Deficiency: Standard

Corresponds to: OME

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In addition to meeting the conditions of participation at §418.10 through §418.116, a hospice that provides hospice care to residents of a SNF/NF or ICF/MR must abide by the following additional

standards.

CoP Standard	Tag	Corresponds to	Deficiency
§418.112(d)(2)	L775	OME - PC.01.03.01/EP41	Standard

Chapter:

**Environment of Care** 

Program:

Hospital Accreditation

Standard:

EC.02.01.01

**Standard Text:** 

The hospital manages safety and security risks.

Primary Priority Focus Area: Physical Environment

**Element(s) of Performance:** 

5. The hospital maintains all grounds and equipment.



Scoring

Category:

С

Score:

Partial Compliance

#### Observation(s):

§482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

This Standard is NOT MET as evidenced by:

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

Observed that multiple isolation room exhausts on the roof were not labeled as hazardous.

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

Observed that the Pathology hood exhaust on the roof was not labeled as hazardous.

Chapter:

**Environment of Care** 

Program:

Hospital Accreditation

Standard:

EC.02.03.05

ESC 60 days

ESC 60 day

**Standard Text:** 

The hospital maintains fire safety equipment and fire safety building features. Note: This standard does not require hospitals to have the types of fire safety equipment and building features described below. However, if these types of equipment or features exist within the building, then the following

maintenance, testing, and inspection requirements apply.

Primary Priority Focus Area: Information Management

## **Element(s) of Performance:**

25. For hospitals that use Joint Commission accreditation for deemed status purposes: Documentation of maintenance, testing, and inspection activities for fire alarm and water-based fire protection systems includes the following:



- Name of the activity
- Date of the activity
- Required frequency of the activity
- Name and contact information, including affiliation, of the person who performed the activity
- NFPA standard(s) referenced for the activity
- Results of the activity

Note: For additional guidance on documenting activities, see NFPA 25, 1998 edition (Section 2-1.3) and NFPA 72, 1999 edition (Section 7-5.2).

Scoring

Category:

Score:

Partial Compliance

## Observation(s):

FP 25

§482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101®2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal\_register/code\_of\_federal\_regulations/ibr\_locations.html.

Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

This Standard is NOT MET as evidenced by:

Observed in Document Review at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

During the Document Review session it was found that the contracted vendors annual and quarterly fire alarm testing/inspection documentation did not include the NFPA standard(s) referenced for the activity(s) performed.

Observed in Document Review at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

During the Document Review session it was found that the contracted vendors annual and quarterly fire suppression system testing/inspection documentation did not include the NFPA standard(s) referenced for the activity(s) performed.

Chapter:

**Environment of Care** 

Program:

Hospital Accreditation

Standard:

EC.02.05.01

ESC 60 days

Standard Text:

The hospital manages risks associated with its utility systems.

Primary Priority Focus Area: Physical Environment

# **Element(s) of Performance:**

1. The hospital designs and installs utility systems that meet patient care and operational needs. (See also EC.02.06.05, EP 1)



Scoring

Category:

Score:

Insufficient Compliance

# Observation(s):

EP 1

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. Observed in the third floor Medical Gas Cylinder storage room, where greater than 3000 cuft. of gas was being stored, that the Mechanical Exhaust system was not a dedicated exhaust.

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. Observed in the third floor Medical Gas Cylinder storage room, where greater than 3000 cuft. of gas was being stored, that the Mechanical Exhaust system fan motor was not on a critical electrical circuit.

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. Observed in the third floor Medical Gas Cylinder storage room, where greater than 3000 cuft. of gas was being stored, that the Mechanical Exhaust system inlet grills were in the ceiling. The inlet grills for the exhaust must be within 1 foot of the floor and unobstructed.

Chapter:

**Environment of Care** 

Program:

Hospital Accreditation

Standard:

EC.04.01.01

ESC 45 days

**Standard Text:** 

The hospital collects information to monitor conditions in the environment.

Primary Priority Focus Area: Quality Improvement Expertise/Activities

#### Element(s) of Performance:

15. Every 12 months, the hospital evaluates each environment of care management plan, including a review of the plan's objectives, scope, performance, and effectiveness. (See also EC.01.01.01, EPs 3-8; EC.04.01.03, EP 1)



Scoring

Category:

Score:

Insufficient Compliance

#### Observation(s):

§482.41(a) - (A-0701) - §482.41(a) Standard: Buildings

The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

This Standard is NOT MET as evidenced by:

Observed in Environment of Care Session at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

During the Environment of Care session, it was found that the organization had reviewed their plans and it was evident that the organization had reviewed the Objectives and Performance of each plan, but was not evident that they had reviewed the Scope and Effectiveness of each plan.

Chapter:

Human Resources

Program:

Hospital Accreditation

Standard:

HR.01.04.01

ESC 60 days

**Standard Text:** 

The hospital provides orientation to staff.

Primary Priority Focus Area: Orientation & Training

**Element(s) of Performance:** 

7. The hospital orients external law enforcement and security personnel on the following:



- How to interact with patients

- Procedures for responding to unusual clinical events and incidents
- The hospital's channels of clinical, security, and administrative
- Distinctions between administrative and clinical seclusion and restraint

Scoring

Category:

Score:

Partial Compliance

## Observation(s):

Observed in Tracer Activities in the ER at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. During a visit to the Emergency Room (ER), document review, and numerous discussions, it was determined that the orientation and education of external law enforcement personnel (as addressed in the Care of Law Enforcement Patients policy EOC.SEC.020) was not being done in the ER. The policy stated that "Officers who are guarding a prisoner will receive "An Officer Orientation Sheet" ... " The director of security could not say that the Officer Orientation Sheet was consistently being distributed in the ER according to the policy. After asking about this process in the ER, the survey coordinator reported that the nursing staff were not using the Officer Orientation Sheet.

Observed in Tracer Activities in ER at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. Small sample size.

Chapter:

Infection Prevention and Control

Program:

Hospital Accreditation

Standard:

IC.02.02.01

**Standard Text:** 

The hospital reduces the risk of infections associated with medical

equipment, devices, and supplies.

Primary Priority Focus Area: Infection Control

# Element(s) of Performance:

2. The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. \* (See also EC.02.04.03, EP 4)



Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes.

Footnote \*: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at

http://www.cdc.gov/hicpac/Disinfection\_Sterilization/acknowledg.html (Sterilization and Disinfection in Healthcare Settings).

Scoring

Category:

Α

Score:

Insufficient Compliance

4. The hospital implements infection prevention and control activities when doing the following: Storing medical equipment, devices, and supplies.



Scoring

Category:

C

Score:

Partial Compliance

# Observation(s):

EP 2

§482.51 - (A-0940) - §482.51 Condition of Participation: Condition of Participation: Surgical Services This Condition is NOT MET as evidenced by:

Observed in Tracer Activities at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

It was observed in the Newborn Nursery Isolation Room, where circumcisions are performed, that sterile gomko instruments had been double packaged in paper-plastic pouches with the inner sealed pouch requiring folding to make it fit into the outer pouch. This is contrary to current standards for proper instrument packaging and processing.

EP 4

§482.42 - (A-0747) - §482.42 Condition of Participation: Condition of Participation: Infection Control This Condition is NOT MET as evidenced by:

Observed in Tracer Activities at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

During tracer activity in the Women's Center, it was noted in Triage Room 241, that multiple hemocult cards had expired 11/12. In addition, multiple gen probes had expired 5/31/13. It was also noted in the Clean Utility Room that two angiocaths had expired 2012 and 2013, but remained on the shelf available for use.

Observed in Tracer Activities on MS2 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the pediatric examination room, it was noted that there were 15 units of "strep and flu swabs" that were outdated (i.e. expiration date 4/2013).

**Chapter:** 

Leadership

Program:

Hospital Accreditation

Organization Identification Number: 7910

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Standard:

LD.04.01.01

ESC 60 days

Standard Text:

The hospital complies with law and regulation.

Primary Priority Focus Area: Communication

Element(s) of Performance:

2. The hospital provides care, treatment, and services in accordance with licensure requirements, laws, and rules and regulations.



Scoring

Category:

Score:

Insufficient Compliance

Observation(s):

Observed in Individual Tracer at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. During tracer activity and review of the record of care for the process for documenting the administration of Hepatitis B vaccines, it was noted that the staff do not document the version of the vaccine information sheet in the medical record as required by the National Childhood Vaccine Injury Act.

Chapter:

Life Safety

Program:

Hospital Accreditation

Standard:

LS.02.01.10

ESC 45 days

Standard Text:

Building and fire protection features are designed and maintained to

minimize the effects of fire, smoke, and heat.

Primary Priority Focus Area: Physical Environment

**Element(s) of Performance:** 

1. Buildings meet requirements for height and construction type in accordance with NFPA 101-2000; 18/19.1.6.2.



Scoring

Category:

Score:

Insufficient Compliance

Observation(s):

#### EP 1

§482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101®2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal\_register/code\_of\_federal\_regulations/ibr\_locations.html.

Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

This Standard is NOT MET as evidenced by:

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

Observed in the Penthouse Mechanical space, the structural steel spray coating had been removed in multiple areas to accommodate clamps and or pipes and was not re-insulated.

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

Observed in the Physical Plant space, the structural steel spray coating had been removed in multiple areas to accommodate clamps and or pipes and was not re-insulated.

Chapter:

Life Safety

Program:

Hospital Accreditation

Standard:

LS.02.01.35

ESC 60 days

Standard Text:

The hospital provides and maintains systems for extinguishing fires.

Primary Priority Focus Area: Physical Environment

Element(s) of Performance:

5. Sprinkler heads are not damaged and are free from corrosion, foreign materials, and paint. (For full text and any exceptions, refer to NFPA 25-1998: 2-2.1.1)



Scoring

Category:

Score:

Insufficient Compliance

14. The hospital meets all other Life Safety Code automatic extinguishing requirements related to NFPA 101-2000: 18/19.3.5

Scoring

Category:

Score:

Partial Compliance

Observation(s):

EP 5

§482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101®2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal\_register/code\_of\_federal\_regulations/ibr\_locations.html.

Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

This Standard is NOT MET as evidenced by:

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

Observed in the #4 radiology room were fire suppression heads coated with a thick layer of dust.

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

Observed in the #3 radiology room were fire suppression heads coated with a thick layer of dust.

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

Observed in the Same Day Surgery suite were fire suppression heads coated with a thick layer of dust.

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

Observed in the Cardiac Rehabilitation area were fire suppression heads coated with a thick layer of dust.

#### FP 14

§482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101®2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal\_register/code\_of\_federal\_regulations/ibr\_locations.html.

Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

This Standard is NOT MET as evidenced by:

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

Observed in the Cardiac Rehabilitation storage room were missing ceiling tiles.

Observed in Building Tour at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

Observed in the radiology waiting room was a fire suppression head missing its escutcheon ring. This was corrected during the survey.

Chapter:

Medical Staff

Program:

Hospital Accreditation

Standard:

MS.08.01.01

ESC 60 days

Standard Text:

The organized medical staff defines the circumstances requiring monitoring

and evaluation of a practitioner's professional performance.

Primary Priority Focus Area: Credentialed Practitioners

**Element(s) of Performance:** 

1. A period of focused professional practice evaluation is implemented for all initially requested privileges.



Scoring

Category:

Score:

Insufficient Compliance

#### Observation(s):

EP 1

Observed in Credentialing and Privileging at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN)

During a review of a completed Focused Professional Practice Evaluation(FPPE) period for a newly appointed radiologist, the documents provided to show the completion of the FPPE did not indicate that the process was privilege specific. For example, the radiologist had kyphoplasty privileges, but a review of the procedures that he performed during the period of the FPPE did not indicate that a kyphoplasty had been done; and therefore, could not have been evaluated. This privilege did not appear to be grouped with any similar privilege. Also, one could not determine whether the privilege for moderate sedation had been evaluated during the FPPE. In the FPPE documents of a newly appointed cardiologist, one could determine that the cardiologist had taken care of a specific number of patients with chest pain, but could not determine whether this involved cardiac catheterization with or without stent insertions; with or without moderate sedation. During the discussion, the physicians present agreed that the FPPE process needed to be more privilege specific, with documentation that could demonstrate the evaluation of specific privileges during the FPPE. The FPPE policy did not provide any information concerning the need to evaluate each new privilege, or group of very similar activities, during the FPPE.

Chapter:

Medical Staff

Program:

Hospital Accreditation

Standard:

MS.08.01.03

ESC 60 days

Standard Text:

Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privilege(s), or to

revoke an existing privilege prior to or at the time of renewal.

Primary Priority Focus Area: Credentialed Practitioners

#### Element(s) of Performance:

1. The process for the ongoing professional practice evaluation includes the following: There is a clearly defined process in place that facilitates the evaluation of each practitioner's professional practice.



Scoring

Category:

Α

Score:

Insufficient Compliance

3. The process for the ongoing professional practice evaluation includes the following: Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege(s).



Scoring

Category:

Α

Score:

Insufficient Compliance

#### Observation(s):

FP 1

§482.22(a)(1) - (A-0340) - (1) The medical staff must periodically conduct appraisals of its members.

This Standard is NOT MET as evidenced by:

Observed in Credentialing and Privileging at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

The policy for the Ongoing Professional Practice Evaluation (OPPE) did not address a number of the components addressed in the FAQ for the OPPE. The discussion indicated that the Quality Department forwarded quality data to the department chiefs quarterly, but the data only addressed the physicians that "trended out" during the data collection. The only documentation of any decisions by the department chiefs for the majority of physicians would occur at the two year reappointment. The policy did not provide for the evaluation of all of the practitioners on a frequency that was ongoing (less than every 12 months). Although the organization was collecting data on the individual practitioners, the methods used to evaluate the practitioners did not comply with the requirements of this Element of Performance; and therefore, did not provide the necessary "clearly defined process".

#### EP 3

§482.22(a)(1) - (A-0340) - (1) The medical staff must periodically conduct appraisals of its members.

This Standard is NOT MET as evidenced by:

Observed in Credentialing and Privileging at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

The Ongoing Professional Practice Evaluation (OPPE) process did not include all the practitioners in documented evaluations by the department chiefs at intervals of less than every 12 months. The Quality Department presented to the department chiefs the data on those practitioners that "trended out" based on the established criteria. It was only at appointment that all of the practitioners would be evaluated by the department chiefs, and have documented decisions concerning the status of the practitioners' privileges. The organization's OPPE policy did not comply with the requirements of the standard to evaluate and document decisions for all of the practitioners at a frequency of less than 12 months. Only the practitioners that "trended out" during the Quality Department's analysis were being evaluated more frequently than every two years by the department chiefs. The OPPE file of a general surgeon had quarterly data, but did not have a review and a documented decision by a department chief since he did not "trend out" on any of the criteria being reviewed.

Chapter:

Medical Staff

Program:

Hospital Accreditation

Standard:

MS.11.01.01

ESC 60 days

**Standard Text:** 

The medical staff implements a process to identify and manage matters of individual health for licensed independent practitioners which is separate

from actions taken for disciplinary purposes.

Primary Priority Focus Area: Communication

Element(s) of Performance:

1. Process design addresses the following issues: Education of licensed independent practitioners and other organization staff about illness and impairment recognition issues specific to licensed independent practitioners (at-risk criteria).



Scoring

Category:

Score:

Insufficient Compliance

Observation(s):

Observed in Credentialing and Privileging at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN)

The organization did not provide evidence of education of the licensed licensed practitioners about illness and impairment recognition issues specific to licensed independent practitioners (at-risk criteria).

Chapter:

Medication Management

Program:

Hospital Accreditation

Standard:

MM.03.01.01

ESC 45 days

Standard Text:

The hospital safely stores medications.

Primary Priority Focus Area: Medication Management

**Element(s) of Performance:** 

7. All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.



Scoring

Category:

Score:

Partial Compliance

Observation(s):

Observed in Tracer Activities at NorthCrest Medical Center (2536 Highway 49, Pleasant View, TN) site. During tracer activity in the CT imaging area, it was noted that Isovue contrast located in a warmer was labeled with the date the contrast was placed in the warmer, rather than the expiration date.

Observed in Tracer Activities on MS3 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. During a tour of the medication room, it was noted that a liter bag of D5NS IV fluid had been removed from the overwrap; but a new expiration date was not documented on the bag. When the IV bag was removed from the overwrap, a new expiration date based on the size of the bag should have been marked on the bag. There was also a 50 ml bag of NS that had been removed from the overwrap, but did not have a new expiration date marked on the bag.

Chapter:

Medication Management

Program:

Hospital Accreditation

Standard:

MM.03.01.03

ESC 45 days

Standard Text:

The hospital safely manages emergency medications.

Primary Priority Focus Area: Patient Safety

Element(s) of Performance:

2. Emergency medications and their associated supplies are readily accessible in patient care areas. (See also PC.03.01.01, EP 8)



Scoring

Category:

Score:

Insufficient Compliance

#### Observation(s):

Observed in Tracer Activities at NorthCrest Medical Center (2536 Highway 49, Pleasant View, TN) site. During tracer activity in the CT imaging area, the process for emergency medications and supplies was reviewed. It was observed in the Radiology Department Reaction Kit that all of the medications contained in the kit had expired to include the following: (2) Epi pens, dated 8/12 and 9/12; Epinephrine vials, dated 8/12; 0.9 Sodium Chloride vial dated 1/13; Flumazenil dated 10/12; Diphenhydramine dated 5/13; (2) Epinephrine injections 1:1000 dated 12/12; and (2) Naloxone dated 4/13. In addition, the following supplies had expired: (2) 22 guage IV catheters dated 12/10; and (2) 20 guage IV catheters dated 11/12, and multiple needles dated 1/12.

Observed in Tracer Activities at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. During tracer activity in the CT imaging area and review of the process of emergency medications and supplies, it was observed in the Medication Reaction Kit that two IV catheters had expired in 2007. In addition, in the Airway management kit, the arterial blood sample kit had expired 5/11.

Chapter:

National Patient Safety Goals

Program:

Hospital Accreditation

Standard:

UP.01.03.01

ESC 45 days

Standard Text:

A time-out is performed before the procedure.

Primary Priority Focus Area: Patient Safety

Element(s) of Performance:

5. Document the completion of the time-out.

Note: The hospital determines the amount and type of documentation.



Scoring

Category:

Score:

Partial Compliance

#### EP 5

Observed in Individual Tracer on MS2 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. In the record of a patient recovering from joint surgery, there was no documentation of the time of the "time out" for the nerve block administered in the PACU before the procedure. The organization's Surgical Site & "Time Out" Process policy (SRG.OR.019) indicated on page 3 that the time of the "time out" or pause must be recorded in the record.

Observed in Individual Tracer in the PACU at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN)

In the record of another patient (recovering from a total knee replacement), there was no documentation of a "time out" for the sciatic nerve block administered in the PACU after the procedure. the physician indicated that the "time out" was done, but was not documented at the time.

Chapter:

Provision of Care, Treatment, and Services

Program:

Hospital Accreditation

Standard:

PC.01.02.03

ESC 60 days

Standard Text:

The hospital assesses and reassesses the patient and his or her condition

according to defined time frames.

Primary Priority Focus Area: Assessment and Care/Services

Element(s) of Performance:

5. For a medical history and physical examination that was completed within 30 days prior to registration or inpatient admission, an update documenting any changes in the patient's condition is completed within 24 hours after registration or inpatient admission, but prior to surgery or a procedure requiring anesthesia services. (See also MS.03.01.01, EP 8; RC.02.01.03, EP 3)



Scoring

Category:

Score:

Insufficient Compliance

#### EP 5

§482.24(c)(4)(i)(B) - (A-0461) - (4) [All records must document the following, as appropriate:

- (i) Evidence of --]
- (B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

This Standard is NOT MET as evidenced by:

Observed in Individual Tracer on MS2 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient recovering from a joint replacement, the documentation of the update to the History and Physical (H&P) did not indicate that the H&P had been reviewed. In addition to the documentation that the patient had been examined and that there were no changes, the fact that the H&P was reviewed should have been noted in the update..

Observed in Individual Tracer in the PACU at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient recovering from a knee arthroscopy, the documentation of the update to the History and Physical (H&P) did not indicate that the H&P had been reviewed. In addition to the documentation that the patient had been examined and that there were no changes, the fact that the H&P was reviewed should have been noted in the update..

Observed in Individual Tracer in Endoscopy at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient who had an EGD and colonoscopy, the documentation of the update to the History and Physical (H&P) did not indicate that the H&P had been reviewed. In addition to the documentation that the patient had been examined and that there were no changes, the fact that the H&P was reviewed should have been noted in the update..

Chapter:

Provision of Care, Treatment, and Services

Program:

Hospital Accreditation

Standard:

PC.01.02.07



Standard Text:

The hospital assesses and manages the patient's pain-

Primary Priority Focus Area: Assessment and Care/Services

**Element(s) of Performance:** 

3. The hospital reassesses and responds to the patient's pain, based on its reassessment criteria.



Scoring

Category ::

Score:

Partial Compliance

#### EP 3

Observed in Individual Tracer on MS2 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. In the record of a patient with a fractured hip, there was no documentation of a pain assessment prior to the administration of the pain medication morphine.

Observed in Individual Tracer on MS3 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. In the record of a patient recovering from a joint replacement, there was no documentation of a pain assessment prior to and after the administration of a pain medication.

Chapter:

Provision of Care, Treatment, and Services

Program:

Hospital Accreditation

Standard:

Standard Text:

PC.02.01.11

Resuscitation services are available throughout the hospital.

Primary Priority Focus Area: Patient Safety

Element(s) of Performance:

2. Resuscitation equipment is available for use based on the needs of the population served.

ESC 45 days

(ESC 45 days)

Note: For example, if the hospital has a pediatric population, pediatric resuscitation equipment should be available. (See also EC.02.04.03, EPs 2 and 3)

Scoring

Category:

Score:

Insufficient Compliance

#### Observation(s):

EP 2

Observed in Tracer Activities at NorthCrest Medical Center (2536 Highway 49, Pleasant View, TN) site. During tracer activity in the CT Imaging area, it was observed that an AED located in a locked cabinet contained defibrillator pads that had expired 10/12.

Chapter:

Provision of Care, Treatment, and Services

Program:

Hospital Accreditation

Standard:

Standard Text:

PC.03.01.03

The hospital provides the patient with care before initiating operative or other

high-risk procedures, including those that require the administration of

moderate or deep sedation or anesthesia.

Primary Priority Focus Area: Assessment and Care/Services

#### Element(s) of Performance:

1. Before operative or other high-risk procedures are initiated, or before moderate or deep sedation or anesthesia is administered: The hospital conducts a presedation or preanesthesia patient assessment. (See also RC.02.01.01, EP 2)



Scoring

Category:

Score:

Insufficient Compliance

#### Observation(s):

EP 1

Observed in Individual Tracer in the PACU at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN)

In the record of a patient recovering from a total knee replacement, the preanesthesia evaluation was not complete. The section of the preanesthesia evaluation form that addressed the heart and lung examination was not completed. The organization was informed by an anesthesiologist that the heart and lung examination should have been completed. The patient had a history of hypertension, sleep apnea, and tobacco use.

Observed in a closed record from the ER at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. In the record of a patient who had a chest tube inserted with moderate sedation (in the Emergency Room), the presedation assessment was not completed according to the Moderate Sedation policy (PC.136, pages 4 and 5) (3/2013). There was no documentation of the ASA physical status scale or the NPO status.

Observed in a closed record from the ER at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. In the record of a child who had a facial injury treated with moderate sedation (in the Emergency Room), the presedation assessment was not completed according to the Moderate Sedation policy (PC.136, pages 4 and 5) (3/2013). There was no documentation of the ASA physical status scale.

Observed in Individual Tracer in the CCU at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. In the record of a patient recovering from a PEG procedure, the preanesthesia evaluation did not include completion of the heart and lung physical examination. After a discussion with the anesthesiologist, it was determined that the section of the preanesthesia evaluation form with the heart and lung examination should have been completed.

Observed in Individual Tracer on MS3 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. In the record of a patient that had an IVC filter inserted in the cath lab with moderate sedation, there was no documentation of the ASA physical status. The documentation for the moderate sedation did not include information concerning the ASA status.

Chapter:

Provision of Care, Treatment, and Services

Program:

Hospital Accreditation

Standard:

PC.03.01.05

Standard Text:

The hospital monitors the patient during operative or other high-risk

procedures and/or during the administration of moderate or deep sedation or

ESC 45 days

anesthesia.

Primary Priority Focus Area: Assessment and Care/Services

#### **Element(s) of Performance:**

1. During operative or other high risk procedures, including those that require the administration of moderate or deep sedation or anesthesia, the patient's oxygenation, ventilation, and circulation are monitored continuously. (See also RC.02.01.03, EP 8)



Scoring

Category:

Score:

Insufficient Compliance

#### Observation(s):

EP 1

Observed in Record Review at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. During tracer activity and review of the record of care, it was noted that the patient received procedural sedation. There was no documentation to support the monitoring of the patient's level of consciousness, vital signs, and ETCO2 every 5 minutes as required by hospital policy PC.136 "Moderate Sedation (sedation analgesia)".

Chapter:

Provision of Care, Treatment, and Services

Program:

Hospital Accreditation

Standard:

PC.04.01.05

ESC 45 days

Standard Text:

Before the hospital discharges or transfers a patient, it informs and educates

the patient about his or her follow-up care, treatment, and services.

Primary Priority Focus Area: Communication

#### **Element(s) of Performance:**

8. The hospital provides written discharge instructions in a manner that the patient and/or the patient's family or caregiver can understand. (See also RI.01.01.03, EP 1)



Scoring

Category:

C

Score:

Partial Compliance

#### Observation(s):

Observed in a closed ER record at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. In the outpatient record of a child who had moderate sedation during the treatment of a facial injury in the Emergency Room, the discharge instructions did not provide any information related to the Ketamine 70 mg administered during the procedure. In other areas of the hospital where moderate sedation was administered, discharge information concerning the sedation administered was provided.

Observed in a closed ER record at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site. In the outpatient record of a child who had moderate sedation during the removal of a foreign body from an ear (in the Emergency Room), the discharge instructions did not provide any information related to the Ketamine 70 mg and Versed 2 mg administered during the procedure. In other areas of the hospital where moderate sedation was administered, discharge information concerning the sedation administered was provided.

Chapter:

Record of Care, Treatment, and Services

Program:

Hospital Accreditation

Organization Identification Number: 7910

Page 23 of 34

Standard:

RC.01.01.01

(ESC 60 days

**Standard Text:** 

The hospital maintains complete and accurate medical records for each

individual patient.

Primary Priority Focus Area: Information Management

**Element(s) of Performance:** 

19. For hospitals that use Joint Commission accreditation for deemed status purposes: All entries in the medical record, including all orders, are timed.



Scoring

Category:

Score:

Insufficient Compliance

11. All entries in the medical record are dated.



Scoring

Category:

Score:

Insufficient Compliance

#### EP 11

§482.24(c)(1) - (A-0450) - (1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

This Standard is NOT MET as evidenced by:

Observed in Individual Tracer on MS2 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient recovering from a fractured hip, the cardiopulmonary form used to report an ECHO was signed by a physician. However, the documentation did not indicate the date and time of his entry.

Observed in Individual Tracer on MS2 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient recovering from a hip replacement, the Blood and Blood Product Informed Consent was signed by a physician. However, the documentation did not indicate the date and time of his entry.

Observed in Individual Tracer on MS2 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient recovering from a total knee replacement, the progress note describing the nerve block was signed by a CRNA. However, the documentation did not indicate the date and time of the entry.

#### EP 19

§482.24(c)(1) - (A-0450) - (1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

During tracer activity and review of the record of care, it was noted that the Hepatitis B Vaccine consent form had been dated, but not timed.

Observed in Individual Tracer at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

During tracer activity and review of the record of care, it was noted that the Cesarean Section consent form had been dated, but not timed.

Observed in Individual Tracer on MS3 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient recovering from a total knee replacement, the postoperative anesthesia note was signed and dated, but not timed.

Observed in Individual Tracer on MS2 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient recovering from a total knee replacement, the Patient Safety Agreement was signed by a nurse and dated; but documentation did not indicate the time of the entry. The flu risk assessment was signed by the nurse and dated, but the time was not documented.

Chapter: Record of Care, Treatment, and Services

Program: Hospital Accreditation

Standard: RC.01.02.01

Standard Text: Entries in the medical record are authenticated.

Primary Priority Focus Area: Information Management

Organization Identification Number: 7910

Page 25 of 34

ESC 60 days

#### **Element(s) of Performance:**

3. The author of each medical record entry is identified in the medical record.



Scoring

Category:

Score:

Partial Compliance

#### Observation(s):

EP 3

§482.24(c)(1) - (A-0450) - (1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

During tracer activity and review of the record of care, it was noted that the Pre-Anesthesia Assessment for a Cesarean Section patient was not authenticated, dated or timed.

§482.24(c)(2) - (A-0450) - (2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

This Standard is NOT MET as evidenced by:

Observed in Record Review at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

During tracer activity and review of the record of care, it was noted that the physician order for the radiology procedure with sedation was not authenticated, dated, or timed.

Chapter:

Rights and Responsibilities of the Individual

Program:

Hospital Accreditation

Standard:

RI.01.03.01

ESC 60 days

Standard Text:

The hospital honors the patient's right to give or withhold informed consent.

Primary Priority Focus Area: Rights & Ethics

Element(s) of Performance:

13. Informed consent is obtained in accordance with the hospital's policy and processes and, except in emergencies, prior to surgery. (See also RC.02.01.01, EP 4)



Scoring

Category:

Score:

Insufficient Compliance

EP 13

§482.24(c)(4)(v) - (A-0466) - [All records must document the following, as appropriate:]

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

This Standard is NOT MET as evidenced by:

Observed in Individual Tracer on MS2 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient recovering from joint surgery, the consent for the procedure was not signed by the surgeon in the section provided for the physician's signature. On page 2 of the organization's Informed Consent policy (PC.028)(4/2013), the documentation section noted the role of the physician or mid-level practitioner in the informed consent process. The nurses in the Operating Room indicated that the physician should have signed the operative consent form in the appropriate section. During the survey, numerous operative consents were noted to be properly executed with the physician's signature, date, and time documented.

Observed in Individual Tracer in Endoscopy at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient who had a colonoscopy, the consent for the procedure was not signed by the surgeon in the section provided for the physician's signature. On page 2 of the organization's Informed Consent policy (PC.028)(4/2013), the documentation section noted the role of the physician or mid-level practitioner in the informed consent process. The nurses in the Operating Room indicated that the physician should have signed the operative consent form in the appropriate section. During the survey, numerous operative consents were noted to be properly executed with the physician's signature, date, and time documented.

Observed in Closed Endoscopy record at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In a closed endoscopy record of a patient who had a colonoscopy with moderate sedation, the consent for the procedure was not signed by the surgeon in the section provided for the physician's signature. On page 2 of the organization's Informed Consent policy (PC.028)(4/2013), the documentation section noted the role of the physician or mid-level practitioner in the informed consent process. The nurses in the Operating Room indicated that the physician should have signed the operative consent form in the appropriate section. During the survey, numerous operative consents were noted to be properly executed with the physician's signature, date, and time documented.

Observed in Individual Tracer on MS3 at NorthCrest Medical Center (100 Northcrest Drive, Springfield, TN) site for the Hospital deemed service.

In the record of a patient who had an IVC filter inserted, the consent for blood was not signed by the physician. In a record of a patient with anemia and severe cytopenia, the patient received two units of packed red blood cells and two units of platelets. The consent for the blood were not signed by the physician. In the record of a patient requiring a transfusion after surgery for an ectopic pregnancy, the consent for blood was not signed by the physician. The Chief of Staff confirmed that the sections of the blood consents that addressed the physician providing informed consent should have been signed.

Chapter:

Leadership

Program:

Home Care Accreditation

Standard:

LD.04.03.09

ESC 60 days

Standard Text:

Care, treatment, or services provided through contractual agreement are

provided safely and effectively.

Primary Priority Focus Area: Patient Safety

#### Element(s) of Performance:

16. For hospices that elect to use The Joint Commission deemed status option: The hospice retains management responsibility for the contracted services and verifies that they are furnished in a safe and effective manner.



Scoring

Category:

Score:

Insufficient Compliance

Observation(s):

**EP 16** 

§418.100(e) - (L655) - §418.100(e) Standard: Professional management responsibility.

A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. Arranged services must be supported by written agreements that require that all services be--

This Standard is NOT MET as evidenced by:

Observed in Tracer Activities at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

During the patient visit for HV#3, the surveyor noted that the comfort pack was open and contained a syringe labeled ABHR and expired in 2012. The expiration date on the outside of the comfort pack indicated it was to expire 8/3/13. Conversation with the patient's caregiver found that he had not used anything out of the comfort pack but it had been opened when the nurse instructed him on the medications. This was verified by the nurse. During that time and at no time afterwards did the organization note that the medication sent by the contracted compounding pharmacy was expired.

Chapter:

Medication Management

Program:

Home Care Accreditation

Standard:

MM.05.01.11

**Standard Text:** 

The organization safely dispenses medications.

Primary Priority Focus Area: Medication Management

Element(s) of Performance:

2. The organization dispenses medications and maintains records in accordance with law and regulation, licensure, and professional standards of practice.



ESC 60 days

Note: Dispensing practices and recordkeeping include antidiversion strategies.

Scoring

Category:

Score:

Partial Compliance

#### EP 2

Observed in Tracer Activities at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site.

During the patient visit for HV#3, the surveyor noted that the comfort pack contained an unopened bottle of 20mg/1ml Morphine Sulfate. This bottle had been labeled with a patient name that was partially marked out but the first name and middle initial were not patient HV#3. The dispense date on the label was 5/7/13 and the comfort pack was originally dispensed on 2/4/13. It was unclear from discussion with the nurse how the medication was added to the comfort pack or where HV#3's original Morphine Sulfate bottle may have gone. Discussion with the patient caregiver found that he had not used any medication from the comfort pack. The surveyor further found that the organization did have a patient on service who died 5/7/13, who was using morphine sulfate and who's first name, middle initial and ordering physician, matched what was on the bottle present in HV#3's home.

Observed in Record Review at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site.

In review of the medical record for RR#1, the surveyor noted that the patient died on 5/7/13 and notes indicated that she was using 20mg/1ml morphine sulfate for pain. The medication destruction sheet indicated that 5ml of morphine sulfate solution was wasted and witnessed by someone in the home at the time of death. However, another bottle of morphine sulfate labeled with RR#1's name and physician, was discovered during the home visit for a different patient.

**Chapter:** 

Medication Management

Program:

Home Care Accreditation

Standard:

MM.05.01.19

ESC 60 days

**Standard Text:** 

The organization safely manages returned medications.

Primary Priority Focus Area: Information Management

Element(s) of Performance:

11. For hospices that elect to use The Joint Commission deemed status option: At the time when controlled medications are first ordered, authorized staff document in the patient's record that the written policies and procedures for managing controlled medications were provided and discussed.



Scoring

Category:

Score:

Insufficient Compliance

**EP 11** 

§418.106(e)(2)(i)(C) - (L697) - (C) Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

This Standard is NOT MET as evidenced by:

Observed in Tracer Activities at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

In review of the medical record for HV#1, the surveyor did not find where the hospice had documented that the written policies and procedures for managing controlled medications were provided and discussed. This was confirmed by the case manager.

Observed in Record Review at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Sprinafield, TN) site for the Hospice deemed service.

In review of the medical record for RR#4, the surveyor did not find where the hospice had documented that the written policies and procedures for managing controlled medications were provided and discussed. This was confirmed by the case manager

Observed in Discussion with leadership at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

During review of patient home folders and discussion with caregivers, the surveyor found that the organization provided policy and discussed controlled medication destruction with patients and families. However, after reviewing multiple records and discussion with the case manager, the surveyor found that the organization was not aware that the discussion was required to be documented in the medical record.

Chapter:

Provision of Care, Treatment, and Services

Program:

Home Care Accreditation

Standard:

PC.01.03.01

ESC 60 days

Standard Text:

The organization plans the patient's care.

Primary Priority Focus Area: Assessment and Care/Services

Element(s) of Performance:

41. For hospices that elect to use The Joint Commission deemed status option: For hospice care provided to a resident of a Skilled Nursing Facility (SNF), Nursing Facility (NF), or Intermediate Care Facility for the Mentally Retarded (ICF/MR), the hospice plan of care reflects the participation of the hospice, the SNF, NF, or ICF/MR, and the patient and family to the extent possible.



Scoring

Category:

Score :

Insufficient Compliance

§418.112(d)(2) - (L775) - (2) The hospice plan of care reflects the participation of the hospice, the SNF/NF or ICF/MR, and the patient and family to the extent possible.

This Standard is NOT MET as evidenced by:

Observed in Tracer Activities at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

In review of the comprehensive plan of care for HV#2, the surveyor did not find where the plan reflected the participation of the nursing facility. The current update to the comprehensive plan of care included only those services to be performed by the hospice staff. Careplan problems that could have included facility staff participation, such as altered comfort and nutrition only reflected the hospice. Though communication between the hospice and the facility regarding the care needs of the patient was clearly evident during the patient visit, this collaboration was not reflected in the comprehensive plan of care.

**Chapter:** 

Provision of Care, Treatment, and Services

Program:

Home Care Accreditation

Standard:

PC.02.01.01

ESC 45 days

Standard Text:

The organization provides care, treatment, or services for each patient.

Primary Priority Focus Area: Assessment and Care/Services

Element(s) of Performance:

1. The organization provides the patient with care, treatment, or services according to his or her individualized plan of care.



Scoring

Category:

Score:

Partial Compliance

#### Observation(s):

§418.56(e)(2) - (L555) - (2) Ensure that the care and services are provided in accordance with the plan of care. This Standard is NOT MET as evidenced by:

Observed in Patient Home at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

During the home visit for HV#3, the surveyor observed the nurse change the pressure ulcer dressing on the patient's sacrum. The wound was cleansed with wound cleanser, loosely packed with gauze and covered with a tegaderm. The most current order required the gauze dressing to be covered with a dry dressing or mepelix. This same order required a hydrocolloid dressing be used to cover red, irritated skin in the vicinity of the wound. Though the surveyor visualized the patient still had these areas present, no hydrocolloid was applied.

Observed in Record Review at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

During review of the medical record for RR#5, the surveyor found where the nurse had documented wound care using wound cleanser and a loose mepore dressing on 5/6/13. An order for this dressing change procedure was not found in the record.

Chapter:

Record of Care, Treatment, and Services

Program:

Home Care Accreditation

Standard:

RC.01.02.01

Standard Text:

Entries in the patient record are authenticated.

Organization Identification Number: 7910

Page 31 of 34

ESC 60 days

Primary Priority Focus Area: Information Management

**Element(s) of Performance:** 

9. For hospices that elect to use The Joint Commission deemed status option: All entries in the patient records are legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.



Scoring

Category:

Α

Score:

Insufficient Compliance

EP 9

§418.104(b) - (L679) - §418.104(b) Standard: Authentication.

All entries must be legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.

This Standard is NOT MET as evidenced by:

Observed in Tracer Activities at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

In review of the medical record for HV#1, the surveyor noted that the order for Lorazepam dated 12/21, did not contain a route of administration and the order for scopolamine did not contain a dosage. It was also noted that the POST form signed by the patient was incomplete. Sections relating to use of feeding tubes and who the physician discussed the form with, had been left blank.

Observed in Tracer Activities at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

In review of the medical record for HV#2, the surveyor found that orders for lorazepam and fentanyl did not contain a route of administration.

Observed in Record Review at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

In review of the medical record for HV#3, the surveyor found that the order for fentanyl dated 2/21/13 did not contain a route of administration.

Observed in Record Review at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

In review of the medical record for HV#4, the surveyor found that the order for lortab dated 3/15 and the order for Hydrocodone 5/500, did not contain a route of administration.

Observed in Record Review at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

In review of the medical record for RR#2, the surveyor noted that the comprehensive plan of care (CPOC) required the nurse to obtain a pulse oximetry reading every visit. A pulse oximetry reading was not found for the visit dated 5/31/13. In discussion with the nurse, she stated she always performed pulse oximetry readings at the time of the vital signs but in this case she must have failed to complete that entry on her nursing visit note.

Observed in Record Review at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

In review of the medical record for RR#3, the surveyor noted that the comprehensive plan of care (CPOC) required the nurse to obtain a pulse oximetry reading every visit. A pulse oximetry reading was not found for visits dated 4/25/13, 4/29/13, and 5/29/13. In discussion with the nurse, she stated she always performed pulse oximetry readings at the time of the vital signs but in this case she must have failed to complete that entry on her nursing visit notes. This same patient had an order dated 5/8/13 for metoclopromide that was not complete for route of administration.

Observed in Record Review at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

In review of the medical record for RR#4, the surveyor noted that the comprehensive plan of care (CPOC) required the nurse to obtain a pulse oximetry reading every visit. A pulse oximetry reading was not found for the visits dated 4/19/13 and 5/28/13. In discussion with the nurse, she stated she always performed pulse oximetry readings at the time of the vital signs but in this case she must have failed to complete that entry on her nursing visit notes.

Observed in Record Review at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive, Springfield, TN) site for the Hospice deemed service.

In review of the medical record for RR#5, the surveyor found an order for Lortab 7.5/325 dated 5/30/13 that was not complete for route of administration.

Observed in Record Review at NorthCrest Medical Center Home Health and Hospice (101 East Mooreland Drive,

Organization Identification Number: 7910

Page 33 of 34

Springfield, TN) site for the Hospice deemed service.

In review of the medical record for RR#6, the surveyor found an order for Lortab 5/500 dated 5/28/13 that was not complete for route of administration. This same patient had a Physicians Orders for Scope of Treatment (POST) form that was not complete for wishes related to administration of IV fluids and section related to basis for the orders form that was not completed as required.

## **Proof of Publication**

## AFFIDAVIT OF PUBLICATION

0000382412

Newspaper

Robertson County Times

**TEAR SHEET ATTACHED** 

State of Tennessee

**Account Number** 

NAS-282022

Advertiser WALLER LANSDEN DORTCH & DAVIS

RE: NOI - NORTHCREST MEDICAL CENTER

Sales Assistant for the above mentioned newspaper,

hereby certify that the attached advertisement appeared in said newspaper on the following dates;

04/08/15

Subscribed and sworn to before me this \_

**Notary Public** 

forward and make proper settlement with the undersetllement with the under-signed of once. Ronald Roe Holmes, Caro-lyn Holmes Difford, & Marry Angela Beasley-Murray, Co-Executors Lindo R. Koon, Attorney Rosemary E. Phillips, Clerk & Master

Insertion Dales: April 1 & 9, 2015 Public Notices

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City Recorder

NOTICE TO FURNISHERIA
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Co-Executrices Clyde W., Richert, III, Allorney Rosemary E., Phillips,



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Public Notices Public Notices Public Notices

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OGDB369901 NOTICE TO CREDITORS TCA \$30:2-306 Roberston Coumly Son Muin St. Room 103 Courlhose, Springfield, TN 27172 Estate of Rebecca Elizabeth Roberts, De-cressed

Public Notices

REQUEST FOR QUOTATIONS
SEWER FLOW MONITORING EQUIPMENT CITY OF GREENBRIER

SEWER FLOW MONITORING EQUIPMENT

The City of Greenbrier is requesting priced quotolinas
for Wasterware System Flow Monitoring Equipment.
Specifications for the equipment, activate, training,
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Banneth: Davison, Mayor City of Greenbries o

Elizabeth Roberts, December 2

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ROBERTSON COUNTY
BOARD OF ZONING APPEALS
The Roberbox County Buerd of Zoning Agueols will hold its monthly meeting; Thursday, April 23, 2015 at 630 P. An. in the Third Floor Conference Room, Roberton County Office Boilding, Springfield, Tennancee. The following cases will be benefit.

The following cases will be heard.

Case 2015-07 Verizon Wireless and Boverly Davis, www.r.y requests of Special Exception\*\* to install a new wareless communication facility on Chambias Road.

Case 2015-08. "Robin Chis requests on "Special Problem Road.

Robin Chis requests on "Special Problem Road.

Robin Chis requests on "Special Problem Road.

Robin Chis requests on de of Welling in an 1-1 (District) an West Straudville Road.

Case 2015-09. Dustin Selpfords requests a "Special Exception" for a Hame Occupation to operate a was store on Archer Drive.

Case 2015-10 (Problem Road.

Case 2015-10 (Problem Road.

Case 2015-11 (Problem Road.

Case 201

For further information contact Robertson County Plus ning Office 415-384-3666.

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CLASSIFIEDS.

Real Estate Listings, Garage Sales, Employment Ads. Pets.

Telepitroribe, cdf 615-284-2597 or fig or to wave spirmes con for information.

ROBERTSON COUNTY TIMES

0000382412 NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED This is to provide afficient notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. \$48-11-1601 et sea, and the Rules of the Health Services and Development Agency,

Rules of the Health Services and Development Asency WorthCrest Medical Center, Hospital owned by WorthCrest Medical Center with an ownership lyve of WorthCrest Medical Center with an ownership lyve of leads to file an application for a Certificate of Need for leads to file an application for a Certificate of Need for services in Robertson County, Tennessee through In see of a mobile PET unil on the campus of NorthCres Medical Center, NorthCrest Medical Center is located at 100 NorthCrest Drive, Springfield, Tennessee 37172 The cost of this project is expected to be less than 800,000.

13, 2015
The confact person for this project is Kim H, Laoney, Esq., Attarney who may be reached at: Wolfer Landson Dartch & Davis LLP, 511 Union Street, Suite 2708, Nashville, TN 37219 615 (#55-4722

2709, Nozhville, TN 37219 615/1590-2772

Upon written request by inferested parties, a local Foct-Finding public hearing shall be conducted. Written requests for hearing shall be sent to:
Health Services and Market Services and Services an

Securities of the deplication by the Avency.

Securities
SECTION 99 II 11 - ADVERTISEMENT FOR BIDS.
SECTION 99 II 11 - ADVERTISEMENT FOR BIDS.
Society bids for Sidewalk Removal, Woodlend Homes
and Bransferd Heights will be received by Springsfeld.
TN 3712 on Tuesday, April 21st, at 18:66 a.m., set
then, at said effice of the Executive Director abolicly
loops, the agents of all confractors, itself shall be read
action and incorporated into the bid.
The pleas, specifications, and other confract decumpts may be examined of the following locations:
James + Associates, fine.

Long the specification of the following locations:
Con Vantage Woy,
Noshville, TN 3728

joosit checks or drafts shall be made poyable to James H Associates, the State of bidding documents will be furnished to intrinse bidders for deposit property of the state of



# **Letters of Support**



#### LEGISLATIVE OFFICE:

301 6<sup>th</sup> Avenue North Suite 114 War Memorial Building Nashville, TN 37243-0142 Phone (615) 741-2860 rep.sabi.kumar@capitol.tn.gov

## House of Representatives State of Tennessee

DISTRICT OFFICE: 2923 Old South 431 Springfield, TN 37172

## Sabi Kumar REPRESENTATIVE 66TH DISTRICT

Health Services Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

RE:

Certificate of Need Application NorthCrest Medical Center

Dear Board Members,

I write to strongly support for NorthCrest Medical Center's request to provide PET services.

I have been in practice of Surgery at this hospital for the last 37 years. I am proud of the services provided.

Approval of this project will benefit the citizens of Robertson County and will improve the quality of care for our patients. NorthCrest is Springfield's sole community hospital which provides substantial service to the residents of Robertson County and the surrounding areas.

It is crucial that my local hospital has adequate facilities to serve our population, and I believe that local availability of PET services will ensure prompt medical care for all patients.

I respectfully request that you grant a certificate of need to NorthCrest for PET services. Please do not hesitate to contact me for further information. Thank you for your consideration.

Sincerely,

Sabi Kumar, MD



### Robertson County Tennessee Howard R. Bradley County Mayor

108 County Courthouse Springfield, Tennessee 37172 (615) 384-2476 Fax (615) 384-0617

Health Services Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

RE:

Certificate of Need Application NorthCrest Medical Center

To Whom It May Concern:

I am pleased to provide this letter of support for NorthCrest Medical Center's request to provide PET services. Approval of this project will benefit the citizens of Robertson County and will improve the quality of care for our patients.

NorthCrest is Springfield's sole community hospital which provides a substantial service to the residents of Robertson County and the surrounding areas. As a lifelong resident, it is important to me for our hospital to have adequate facilities to serve our population, and I believe that PET services will ensure prompt medical care for all patients.

I respectfully request that you grant a certificate of need to NorthCrest for PET services. Please do not hesitate to contact me for further information. Thank you for your consideration.

Sincerely,

Howard Bradley

Robertson County Mayor

The INBURY

MEDICAL ONCOLOGY/ HEMATOLOGY

Habib Doss, M.D. L. Johnetta Blakely, M.D. Julie Means-Powell, M.D. 4/1/2015

Ms. Melanie Hill, Executive Director Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Certificate of Need Application Re: NorthCrest Medical Center

Dear Ms. Hill:

I am writing this letter in support of NorthCrest Medical Center's request for a Certificate of Need for PET/CT services. I believe providing our community access to PET/CT services in our community would ensure prompt medical care and convenience for all patients.

As a practicing oncologist in this community I anticipate that I would refer an estimated 4 (+/-) patients to that service each month assuming it is available for a half day each week.

I strongly support the CON for PET/CT services, as it is very much needed in our community. If I can be of further assistance, please do not hesitate to let me know.

Sincerely,

Habib Doss, M.D.

#### Southern Radiology Associates 1113 Murfreesboro Road, Suite 106, #343 Franklin, TN 37064

4/1/2015

Ms. Melanie Hill, Executive Director Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Re:

Certificate of Need Application NorthCrest Medical Center

Whai Werly Belin and

Dear Ms. Hill:

I am pleased to provide this letter of support for NorthCrest Medical Center's request for a Certificate of Need for PET/CT services. I am a Diagnostic and Interventional Radiologist practicing at NorthCrest Medical Center. As the Medical Director, I believe approval of this project will benefit my patients, as it would provide our community access to PET/CT services in our community.

NorthCrest is Springfield's sole community hospital that provides a substantial service to the residents of Springfield and surrounding areas. It is very important to me that the hospital has adequate facilities to service our population, and I believe having PET/CT will ensure prompt medical care for my patients.

I respectfully request that you grant a Certificate of Need to NorthCrest Medical Center. If I can be of further assistance, please do not hesitate to let me know.

Sincerely.

Wesley Brewer, M.D.

# Ramesh Chadalavada, MD Springfield Pulmonary & Sleep 221 NorthCrest Drive Springfield, TN 37172

4/1/2015

Ms. Melanie Hill, Executive Director Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Re:

Certificate of Need Application

NorthCrest Medical Center

Dear Ms. Hill:

I am providing this letter in support of NorthCrest Medical Center's request for a Certificate of Need for PET/CT services. I have been practicing as a Pulmonologist Northcrest Medical Center for (14) fourteen years. The hospital must have adequate facilities to serve our population. I believe providing our community access to PET/CT services in our community would ensure prompt medical care and convenience for all patients.

I estimate that I would refer an estimated 2 (+/-) patients to that service each month assuming it is available for a half day each week.

I strongly support the CON for PET/CT services, as it is very much needed in our community. If I can be of further assistance, please do not hesitate to let me know.

Remarchalance MM

Ramesh Chadalavada, M.D.

#### Ronnie Jackson, MD Hospitalist and Pulmonology 496 NorthCrest Drive Springfield TN 37172

4/1/2015

Ms. Melanie Hill, Executive Director Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Re:

Certificate of Need Application NorthCrest Medical Center

Dear Ms. Hill:

I am providing this letter in support of NorthCrest Medical Center's request for a Certificate of Need for PET/CT services. I have been practicing as a Pulmonologist at NorthCrest for (22) twenty-two years. I believe providing our community access to PET/CT services in our community would ensure prompt medical care and convenience for all patients.

As the hospitalist, and an independent practicing physician I estimate that I would refer an estimated 2 (+/-) patients for PET/CT services each month assuming it is available for a half day each week.

I strongly support the CON for PET/CT services, as it is very much needed in our community. If I can be of further assistance, please do not hesitate to let me know.

Sincerely,

Ronnie Jackson/M.D.



Keith Goldberg, MD, FACS A Jonathan Kroser, MD, FACS A Daniel Davis, MD, FACS A Mark Sanders, MD, FACS

General, Endoscopic, Laproscopic, and Vascular Surgery

4/1/2015

Ms. Melanie Hill, Executive Director Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Re:

Certificate of Need Application
NorthCrest Medical Center

Dear Ms. Hill:

I am writing this letter in support of NorthCrest Medical Center's request for a Certificate of Need for PET/CT services. I have been practicing as a General/Vascular Surgeon at Northcrest Medical Center for (12) twelve years. I believe providing our community access to PET/CT services in our community would ensure prompt medical care and convenience for all patients.

I estimate that I would refer an estimated 2 (+/-) patients to that service each month assuming it is available for a half day each week.

I strongly support the CON for PET/CT services, as it is very much needed in our community. If I can be of further assistance, please do not hesitate to let me know.

Sincerely,

Daniel Davis, M.D.



Keith Goldberg, MD, FACS A Jonathan Kroser, MD, FACS A Daniel Davis, MD, FACS A Mark Sanders, MD, FACS

General, Endoscopic, Laproscopic, and Vascular Surgery

4/1/2015

Ms. Melanie Hill, Executive Director Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Re:

Certificate of Need Application NorthCrest Medical Center

Dear Ms. Hill:

I am writing this letter in support of NorthCrest Medical Center's request for a Certificate of Need for PET/CT services. I have been practicing as a General/Vascular Surgeon at Northcrest Medical Center for (6) six years. I believe providing our community access to PET/CT services in our community would ensure prompt medical care and convenience for all patients.

I estimate that I would refer an estimated 2 (+/-) patients to that service each month assuming it is available for a half day each week.

I strongly support the CON for PET/CT services, as it is very much needed in our community. If I can be of further assistance, please do not hesitate to let me know.

Sincerely,

Mark Sanders, M.D.



Keith Goldberg, MD, FACS A Jonathan Kroser, MD, FACS Daniel Davis, MD, FACS A Mark Sanders, MD, FACS

General, Endoscopic, Laproscopic, and Vascular Surgery

4/1/2015

Ms. Melanie Hill, Executive Director Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Re:

Certificate of Need Application NorthCrest Medical Center

Dear Ms. Hill:

I am writing this letter in support of NorthCrest Medical Center's request for a Certificate of Need for PET/CT services. I have been practicing as a General/Vascular Surgeon at Northcrest Medical Center for (14) fourteen years. I believe providing our community access to PET/CT services in our community would ensure prompt medical care and convenience for all patients.

I estimate that I would refer an estimated 2 (+/-) patients to that service each month assuming it is available for a half day each week.

I strongly support the CON for PET/CT services, as it is very much needed in our community. If I can be of further assistance, please do not hesitate to let me know.

Sincerely,

Jonathan Kroser, M.D.



Keith Goldberg, MD, FACS A Jonathan Kroser, MD, FACS Daniel Davis, MD, FACS Mark Sanders, MD, FACS

General, Endoscopic, Laproscopic, and Vascular Surgery

4/1/2015

Ms. Melanie Hill, Executive Director Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Re

Certificate of Need Application
NorthCrest Medical Center

Dear Ms. Hill:

I am writing this letter in support of NorthCrest Medical Center's request for a Certificate of Need for PET/CT services. I have been practicing as a General/Vascular Surgeon at Northcrest Medical Center for (17) seventeen years. I believe providing our community access to PET/CT services in our community would ensure prompt medical care and convenience for all patients.

I estimate that I would refer an estimated 2 (+/-) patients to that service each month assuming it is available for a half day each week.

I strongly support the CON for PET/CT services, as it is very much needed in our community. If I can be of further assistance, please do not hesitate to let me know.

Sincerely,

Keith Goldberg, M.D.

## Dr. Robert Ferland. 2102 Park Plaza Springfield, TN 37172 615-384-9690

Melanie Hill Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Re:

Certificate of Need Application NorthCrest Medical Center

Dear Ms. Hill,

I am providing this letter in support for NorthCrest Medical Center's request for a CON for PET services. I have been a practicing Physician at Northcrest Medical Center for 21 years. I strongly believe PET services would ensure prompt medical care and convenience for all patients in the community. NorthCrest is Springfield's sole community hospital that provides a substantial service to the residents of Springfield and the surrounding areas. It is important that the hospital has adequate facilities to serve our population.

I strongly support the CON for PET services, as it is very much needed in our community. If I can be of further assistance, please do not hesitate to let me know.

Sincerely

Dr Robert Ferland

## Dr. Dennis Rainwater 450 Northcrest Dr. Springfield, TN 37172 615-382-7284

Melanie Hill Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Re: Certificate of Need Application

Dear Ms. Hill,

I am providing this letter in support for NorthCrest Medical Center's request for a CON for PET services. As an active Medical Staff member for 7 years serving Robertson county and the surrounding communities I know the PET service at Northcrest medical Center fulfills a need for our market. As a community hospital we are faced with challenges from surrounding competitors that burden us financially putting our community at risk for less care. Having PET services in our community satisfys a medical need in our community and helps to keep care where it is most effective; at home.

I strongly support the CON for PET services, as it is very much needed in our community. If I can be of further assistance, please do not hesitate to let me know.

Dennis Rienwster mp

Dr. Dennis Rainwater

# Family Healthcare Associates

Melanie Hill Health Service Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

Re: PET Certification for Northcrest Medical Center

Dear Ms. Hill,

As a primary care provider for 32 years I know the effect of local services to the health and wellbeing of a community. Local PET services will provide much needed services to an underserved patient base that is burdened by travel for care.

I strongly support the CON for PET services at Northcrest Medical Center.

Sincerely,

Dr. Michael Lewis

#### WALLER LANSDEN DORTCH & DAVIS LLP

NASHVILLE CITY CENTER
511 UNION STREET, SUITE 2700
POST OFFICE BOX 198966
NASHVILLE, TENNESSEE 37219-8966

Regions Bank General

87-1 640 18715 143

Date:

April 13, 2015

....

\$ \*\*\*3,000.00\*\*\*

PAY TO THE ORDER OF: Health Services and DevelopmentAgency Andrew Jackson Bldg, 9th floor 502 Deaderick Street

Nashville, TN 37243

Memo:

#210877# #064000017#

Client

019783

0001920307

Check #:

210877

Check Date:

April 13, 2015

Payee: Vendor ID:

Inv#

Health Services and DevelopmentAgency

HSDA

Inv Date

4-13-15 KHL-LG 04/13/2015

JΑ

G/L Acct

Matter

52510

<u>Narrative</u>

VENDOR: TN Health Services and Development

Agenc INVOICE#: 4-13-15 KHL-LG DATE:

4/13/2015

Filing Fee - CON for PET Services - NorthCrest

Medical Center

Invoice Totals:

\$3,000.00

**Amount** 

\$3,000.00

\$3,000.00

Inv Total

\$3,000.00

Jamin



Waller Lansden Dortch & Davis, LLP 511 Union Street, Suite 2700 P.O. Box 198966 Nashville, TN 37219-8966 Kim Harvey Looney 615.850.8722 direct

kim.looney@wallerlaw.com

615,244,6380 main 615,244,6804 fax wallerlaw.com

April 30, 2015

# VIA HAND DELIVERY

Ms. Melanie Hill, Executive Director Health Services and Development Agency Andrew Jackson Building, 9<sup>th</sup> Floor 502 Deaderick Street

Re: Certificate of Need Application CN1504-013

NorthCrest Medical Center

#### Dear Melanie:

Please be advised that the applicant requests that the above-referenced application be placed on the consent calendar. The applicant would expect no opposition to this project since it is a sole community hospital and the primary service area contains no PET service currently. Thus, the project involves the initiation of a service not currently provided in the primary service area county.

If you have any questions or need additional information, please do not hesitate to call me.

Sincerely,

Him H. Looney with permission C. Lalen Kim Harvey Looney

KHL:cr



# State of Tennessee Health Services and Development Agency

Andrew Jackson, 9<sup>th</sup> Floor, 502 Deaderick Street, Nashville, TN 37243 www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

May 1, 2015

Kim Looney, Esq. Waller Lansden Dortch & Davis LLP 511 Union Street Suite 2700 Nashville, TN 37219

RE: Certificate of Need Application -- NorthCrest Medical Center - CN1504-013

To initiate a mobile Positron Emission Tomography service (PET) on the Northcrest Medical Center campus at 100 Northcrest Drive in Springfield (Robertson County), Tennessee 37172. The mobile PET service will initially be offered one half day per week (approximately 5 hours while docked) increasing to 2 half days per week. The estimated project cost is \$187,500

Dear Ms. Looney:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need. Please be advised that your application is now considered to be complete by this office.

Your application is being forwarded to Trent Sansing at the Tennessee Department of Health for Certificate of Need review by the Division of Policy, Planning and Assessment. You may be contacted by Mr. Sansing or someone from his office for additional clarification while the application is under review by the Department. Mr. Sansing's contact information is Trent.Sansing@tn.gov or 615-253-4702.

In accordance with Tennessee Code Annotated, §68-11-1601, et seq., as amended by Public Chapter 780, the 60-day review cycle for this project will begin on May 1, 2015. The first sixty (60) days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the sixty (60) day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review within the thirty (30)-day period immediately following. You will receive a copy of their findings. The Health Services and Development Agency will review your application on July 22, 2015.

Kim Looney, Esq. 511 Union Street Suite 2700 May 1, 2015 Page 2

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

- (2) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (3) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,

Melanie M. Hill Executive Director

cc: Trent Sansing, TDH/Health Statistics, PPA

M. Hele

# State\_of\_Tennessee\_ Health Services and Development Agency

Andrew Jackson, 9<sup>th</sup> Floor, 502 Deaderick Street, Nashville, TN 37243 www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

#### **MEMORANDUM**

TO:

Trent Sansing, CON Director

Office of Policy, Planning and Assessment

Division of Health Statistics

Andrew Johnson Tower, 2nd Floor 710 James Robertson Parkway Nashville, Tennessee 37243

oum.

FROM:

Melanie M. Hill

**Executive Director** 

DATE:

May 1, 2015

RE:

Certificate of Need Application

NorthCrest Medical Center - CN1504-013

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a sixty (60) day review period to begin on May 1, 2015 and end on July 1, 2015.

Should there be any questions regarding this application or the review cycle, please contact this office.

Enclosure

cc:

Kim Looney, Esq.



# State of Tennessee Health Services and Development Agency Andrew Jackson Building, 9<sup>th</sup> Floor

Andrew Jackson Building, 9<sup>th</sup> Floor 502 Deaderick Street Nashville, TN 37243

www.tn.gov/hsda

Phone: 615-741-2364 Fax: 615-741-9884

#### **LETTER OF INTENT**

The Publication of Intent is to be publi	shed in the Robertson County Ti	mes	
which is a newspaper of general circu	lation in the county of: Rober		Newspaper
		13011	
Tennessee, on or before	April 8 (County) (Month/Day) , 20 15 (Year)	or one day.	
This is to provide official notice to t accordance with T.C.A. § 68-11-1601		alth Services	and Development Agency, that:
NorthCrest Medical Center (Name of Applicant)		Hospit	al Type-Existing)
	with an owners		
owned by: NorthCrest Medical Center	with an owners		nonprofit corporation
and to be managed by: <u>itself</u>	intends to file a	n application	for a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]: the Tennessee through the use of a mobile Properties of the Pro	<del>`</del>	est Medical Co	enter. NorthCrest Medical Center is
The anticipated date of filing the application.  The contact person for this project is	Cation is: April 13  Kim H. Looney, Esq. (Contact Name)		20 15 Attorney (Title)
who may be reached at: Walle	er Lansden Dortch & Davis LLP (Company Name)	511 Union	Street, Suite 2700 (Address)
Nashville	TN 37219	615	/ 850-8722
(City) 1 0	(State) (Zip Code)	(Area Code	
Din D. Hoone	1 4-8-15	Kim.Loon	ey@wallerlaw.com
(Signature)	(Date)	-	(Email-Address)
The Letter of Intent must be <u>filed in tr</u> last day for filing is a Saturday, Sunda form at the following address: He		ccur on the page of the page o	
The published Letter of Intent must contain the wishing to oppose a Certificate of Need applied	cation must file a written notice with t	he Health Serv	

originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and

Development Agency at or prior to the consideration of the application by the Agency.

HF51 (revised 01/09/2013 – all forms prior to this date are obsolete.)

COPY- ORIGINAL MAILED TO HEACTH SERVICES.



#### **LEGISLATIVE OFFICE:**

301 6<sup>th</sup> Avenue North
Suite 114 War Memorial Building
Nashville, TN 37243-0142
Phone (615) 741-2860
rep.sabi.kumar@capitol.tn.gov

# House of Representatives State of Tennessee

DISTRICT OFFICE: 2923 Old South 431 Springfield, TN 37172

# Sabi Kumar REPRESENTATIVE 66TH DISTRICT

Health Services Development Agency 500 Deaderick Street, Suite 850 Nashville, TN 37243

RF:

Certificate of Need Application NorthCrest Medical Center

Dear Board Members,

I write to strongly support for NorthCrest Medical Center's request to provide PET services.

I have been in practice of Surgery at this hospital for the last 37 years. I am proud of the services provided.

Approval of this project will benefit the citizens of Robertson County and will improve the quality of care for our patients. NorthCrest is Springfield's sole community hospital which provides substantial service to the residents of Robertson County and the surrounding areas.

It is crucial that my local hospital has adequate facilities to serve our population, and I believe that local availability of PET services will ensure prompt medical care for all patients.

I respectfully request that you grant a certificate of need to NorthCrest for PET services. Please do not hesitate to contact me for further information. Thank you for your consideration.

Sincerely.

Sabi Kumar, MD



# State of Tennessee Health Services and Development Agency

Andrew Jackson Building, 9th Floor

www.tn.gov/hsda Phone: 615-741-2364/Fax: 615-741-9884

April 15, 2015

Kim Harvey Looney Waller Landsden Dortch & Davis LLP 511 Union Street, Suite 2700 Nashville, TN 37172

RE: Certificate of Need Application CN1504-013

Northcrest Medical Center - Initiation of PET Service on Hospital Campus

Dear Ms. Looney,

This will acknowledge our April 13, 2015 receipt of your application for a Certificate of Need for the initiation of a Positron Emission Tomography service (PET) on the Northcrest Medical Center campus at 100 Northcrest Drive in Springfield (Robertson County), Tennessee 37172.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

<u>Please submit responses in triplicate by 1:00 PM, April 22, 2015.</u> If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

# 1. Section A, Applicant Profile, Item 9

Please provide a bed complement table for the response and submit as replacement page 4 of the application.

# 2. Section B, Applicant profile, Item 13

An immediate benefit of the project appears to be participation in the hospital's PET service by members of Southern Radiology Associates. With respect to payment for services, review of Item 1.3.6 of the former contract between the applicant and the hospital appears to confirm coordination of insurance benefits between the parties pertaining to participation by SRA in Medicare, Medicaid and other insurance plans in which the hospital participates. Review of Item 1.9 reflects that SRA must accept assignment of Medicare and Medicaid benefits on all Medicare and Medicaid patients. Given the expiration of the former agreement on 2/1/2015 and no replacement documentation for same such as a draft working agreement between the parties, please describe the arrangement planned for the proposed service. Will the hospital bill on a global basis, collect payments for services and reimburse the SRA radiologists on some prearranged basis?

billing separately, it would be helpful to include names, medical and provider license numbers of the SRA radiologists involved in this regard.

## 3. Section B, Project Description, Item I

The executive summary is noted. Please provide brief remarks that identify the ownership structure, the need for the mobile service based on the extent of resident outmigration for PET services at other provider locations, and a brief description of the financial performance of the project in terms of sustainability of the service in light of the hospital's unfavorable net operating income reflected in the Historical Data Chart and audited financial statements (Statement of Operations) provided in the application.

Please explain in more detail why the hospital and the equipment vendor did not know that PET was a reviewable Certificate of Need service immediately prior to or during the 17 months the mobile PET service was operated at Northcrest Medical Center.

# 4. Section B, Project Description, Item II.C

The applicant states that the oncology services provided to residents of Robertson County have increased in recent years. However, review of the hospital's 2013 Joint Annual Report (JAR) revealed that the hospital did not provide chemotherapy services or radiation therapy services during the period. Additionally, surgery volumes related to cancer cannot be determined from the JAR. As such, additional description of the hospital's cancer program is needed. Please address the following items:

A) The incidence of cancer in Robertson County compared to statewide rates using information available through the Tennessee Department of Health

B) The nature and scope of the hospital's existing cancer programs through its participation in the Vanderbilt Health Affiliate Network (VHAN).

C) A description of the hospital/medical staff organizational structure for coordinating the activities of the oncology program,

 A description of the hospital's tumor registry and tumor board and information systems support for these activities

E) A description of how the proposed PET service can contribute to any clinical investigative protocols through formal oncology network relationships with other providers.

The applicant states that the previous service averaged approximately 8 PET procedures per month from September 2013 through February 2015. At that rate, it appears that approximately 136 PET procedures were performed during the 17 month period in lieu of the 227 procedures (average of 13 per month) indicated in your response on page 9 of the application. Please clarify.

Review of HSDA Equipment Registry records revealed that residents of Robertson County had approximately 266 PET procedures at Tennessee provider locations in calendar year (CY) 2013, excluding PET utilization of Robertson County residents at Northcrest during the 12-month period. Assuming residents of the county had approximately 100 scans at Northcrest in CY2013 (8 per month x 12 months), it would appear that the residents had approximately 366 PET procedures in 2013. With this in mind, the applicant's projections for 475 PET procedures in Year 1 (2015) increasing by 21% to 573 procedures in Year 2 appear

to exceed resident demand for the service. Please explain how utilization by residents of the county can support the projected volumes identified for the proposed 2-3 day per week mobile service.

## 5. Section B, Project Description, Item II.E.

<u>Item 2.a</u> – Please provide the name of the unit, year manufactured, and date acquired by the vendor. Excluding downtime for maintenance, how long has the mobile unit been in use?

Please identify all existing sites of the proposed mobile unit, distance from the applicant and days of week they are scheduled.

<u>Item 2.b</u> – the applicant states that the service may be provided up to 3 days per week to meet the needs of service area residents. Please explain why this is necessary when the prior service operated 1 day per week over the 17 months ending February 2015.

<u>Item 2.c</u> – The applicant states that the cost of the lease has not yet been determined. At a minimum, documentation of the equipment lease should be provided in the form of a Letter of Intent between the hospital and the equipment vendor in lieu of the expired lease agreement used for the previous arrangement. Please clarify by providing the documentation requested to support the Project Cost of the application.

Who does the equipment vendor use to obtain the FDG/radioactive material at the cost of \$150 per dose? Please provide the name of the supplier and address. Please also identify the distance to the closest cyclotron source. Are these costs reflected in the Project Cost Chart on page 20?

<u>Item 2.d</u> - Please provide documentation from the equipment vendor that describes how the \$225,000 fair market value estimate of the mobile unit was determined.

# 6. Section C. Need Item 1. (Project Specific Criteria - PET Service)

Item 1 -Patients with cancer diagnoses appear to account for approximately 78% of the 475 projected PET procedures shown in the table on page 12 for Year 1. Please include the cancer incidence rate of Robertson County residents for the most recent period available in documentation in information maintained by the Department of Health or other sources of population data.

As noted, please justify the increase in PET procedures at the amounts indicated in light of both the applicant's prior utilization and resident PET procedures. For resident PET procedures, please show for 2011 – 2013 by contacting Alecia Craighead, Stat III, HSDA.

Item 4- The referral arrangements with Vanderbilt Ingram Cancer Center and Tennessee Oncology are noted. Given the absence of chemotherapy services and radiation therapy services at Northcrest, what arrangements are planned for referrals to other facilities in contiguous counties such as Davidson County? As part of same, what assurances will be provided for acceptance of PET scans performed by the applicant? Under what circumstances will rescanning be necessary?

**Item 6.c.** – Please also address the hospital's procedures to be implemented in the event of a spill of the radioactive material used for the mobile PET unit. What are the responsibilities of the medical director or appropriate hospital personnel for same?

**Item 6.f.**-it appears that the response would include comment about SRA physicians being active members of the hospital medical staff. Please clarify.

Item 8.b – please include comment here about findings of the cancer incident rate for residents of Robertson County. Please also compare to the statewide average rate for the most recent 12 month period available.

## 7. Section C, Need, Item 3 (Service area)

Please complete the table below documenting resident PET utilization:

	2011	2012	2013
Robertson County			
Resident			
Procedures at all			
TN Provider Sites			
Total Resident MRI			
Procedure Rate per			
1,000 population			
Statewide PET Rate			
per 1,000			
population			

HSDA Equipment Registry, TDH population estimates

#### 8. Section C, Need, Item 5

The absence of other PET providers in Robertson County is noted. Please identify the use of PET providers in Davidson County and other areas of TN by residents of Robertson County for the most recent 3 years. A suggested template is provided in the table below. Please contact Alecia Craighead, HSDA Stat III for assistance with data from the HSDA Equipment Registry.

PET Utilization by Robertson County Residents, 2011-2013

Providers	Provider	Distance	2011	2012	2013	0/0
with PET	Location	from				Change
Service		Applicant				′11-′13
Premier	Davidson					
Imaging	Davidson					
Alliance						
TN Oncology	Davidson					
Centennial	Davidson					
VUMC	Davidson					
Other	Davidson					
Subtotal-						
Davidson						

County			
All other TN			
providers			
Total -TN			

<sup>•</sup> Note: new provider Source: HSDA Equipment Registry, 2013 Service Utilization Records

## 9. Section C, Need. Item 6 (applicant's projected Utilization)

It appears that the applicant is projecting utilization in Year 1 that amounts to approximately 130% of the total estimated utilization of Robertson County residents in 2013. Please explain how this is possible by explaining the methodology that was used to project PET volumes of the project in more detail.

In your response, please summarize the strategies that Northcrest would need to implement to capture all outmigration of residents to providers outside the county. What are the key factors that will determine whether or not the capture rate methodology is attainable?

Please show the percentages by payor for the propose service in Year 1 of the project by completing the table below.

Mobile PET Service Payor Mix, Year 1

Payor Source	Year 1 Gross	Average Gross	Year 1 Gross
	Revenue	Charge per PET	Revenue
	(as a % of total)	procedure	(as a % of total)
Medicare			72
Tenncare			
Managed care			
Commercial			
Self-Pay			
Other			
Total			

# 10. Section C, Economic Feasibility Item 1 (Project Costs Chart)

The following definition regarding major medical equipment cost in Tennessee Health Services and Development Agency Rule 0720-9-.01 (13)(b) states "The cost of major medical equipment includes all costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: (1) maintenance agreements, covering the expected useful life of the equipment; (2) federal, state, and local taxes and other government assessments and (3) installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding."

Is the \$321,360.00 mobile PET unit equipment cost listed in Line A.7 of the Project Cost Chart consistent with the Rule? In your response, please provide a breakout of the key cost items of the fixed unit that apply to the project per

Agency Rule above. If not, please make the necessary equipment cost adjustments and submit a revised Project Cost Chart.

## 11. Section C, Economic Feasibility, Item 4. (Projected Data Chart)

Line D.9 "Other Expenses" appears to be missing the anticipated mobile equipment lease cost with related costs for FDG, and expenses for contract fees with Southern Radiology Associates and/or related professional fees of the radiologists. Please identify same and provide a revised chart in a replacement page for the application labeled 26-R.

Review of the Consolidated Statement of Operations in the attachments revealed differences in the entries for net operating revenue and net operating income from the amounts shown in the Historical Data Chart on page 25. As a result, it appears that the unfavorable net income may be higher than shown in the chart. Please clarify.

## 12. Section C., Economic Feasibility, Item 6 B.

Please include a comparison to HSDA Equipment Registry PET charges in the response.

What are the arrangements for professional fees related to imaging interpretation services by radiologists? Are these reflected in the Projected Data Chart for the mobile service?

#### 13. Section C, Economic Feasibility, Item 11 b.

A key benefit of the proposed service appears to be a more convenient and accessible site for residents of the county. Looking at distance/travel times as a key factor, what are the savings in mileage/driving times to the applicant's campus that residents of the service area could expect?

What other key benefits should residents and their attending physicians be aware of in selecting Northcrest's proposed PET service in lieu of other sites outside the service area?

# 14. Section C, Orderly Development, Item 4

It is understood technical staff will be provided by the equipment vendor. However, please show by position classification.

# 15. Published Letter of Intent (LOI)

The LOI did not identify or otherwise specify the anticipated schedule such as number of days per week that the mobile PET service would be available at Northcrest. Please clarify why this information was omitted.

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." For this application the sixtieth (60<sup>th</sup>) day after written notification is June 17, 2015. If this application is not deemed complete by this date, the application will be deemed void. Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the <u>next review cycle</u>, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. 3 68-11-1607(d):

- (1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please do not hesitate to contact this office.

Sincerely,

Jeff Grimm

Health Examiner

Tennessee Health Services & Development Agency

# COPY SUPPLEMENTAL-2

NorthCrest Medical Center

CN1504-013



Waller Lansden Dortch & Davi April 29152045 ma 511 Union Street, Suite 2700 615.244.6804 fax P.O. Box 198966 3:04 pm allerlaw.com Nashville, TN 37219-8966

April 29, 2015

#### VIA HAND DELIVERY

Jeff Grimm
HSDA Examiner
Health Services and Development Agency
9<sup>th</sup> Floor
502 Deaderick Street
Nashville, TN 37243

RE:

NorthCrest Medical Center CN1504-013 - Initiation of PET Service on Hospital

Campus - Second Supplemental Request

Dear Jeff:

This letter is submitted as the supplemental response to your letter April 23, 2015, wherein additional information or clarification was requested regarding the above-referenced CON application.

# 1. Section B, Project Description, Item I

The explanation for more detail pertaining to the hospital's operation of a mobile PET service without an approved CON during September 2013 to February 2015 is noted.

The applicant states that it had prior approval from the payers, including Medicare and TennCare, to perform all of the PET scans provided. It appears that documentation of CON approval for the mobile PET service may not have been required or covered as a part of the credentialing process between the hospital and all of the payer sources. Please explain how the credentialing process with payers may provide a means to cross check for services requiring approved CONs going forward.

**Response:** The applicant is unclear how the credentialing process with payers could provide a means to cross check for services requiring approved CONs going forward. When a hospital adds a service, there is no notification to Medicare or TennCare required. The service is simply part of the services provided by the hospital going forward.

Since it is now understood that an approved Certificate of Need is required to operate a PET service at the hospital in accordance with state law TCA 68-11-1607, please briefly describe any additional actions the applicant has taken to review its status regarding CON approval for all reviewable equipment and services required under TCA 68-11-1607.

**Response:** The applicant does not believe it is currently providing any services that require CON approval, for which CON approval has not been received.

April 29, 2015 3:04 pm

Waller Jeff Grimm HSDA Examiner April 29, 2015 Page 2

Please also describe actions or plans by NMC executive leadership to notify the payers that the hospital did not have an approved CON to operate a mobile PET service from 9/2013 through 2/2015 for the purpose of cooperating with any requests that may be needed to rectify the matter. In your response, please document the hospital's written notification in this regard, as appropriate.

**Response:** NorthCrest has no current plans to notify the payers that it did not have CON approval to operate a mobile PET service. To the best of its knowledge, there is not a requirement for it to do so.

# 2. Section B, Project Description, Item II.C and Section C, Need, Item 6

The corrected amount indicating that 227 total mobile PET procedures were provided during the 17 month period ending February 2015 is noted (average of 13 per month). Using this rate and adding to the 266 Robertson County resident PET procedures documented in the HSDA Equipment Registry as being performed during the CY2013 period, it appears that the applicant has accounted for approximately 90% of the total projected utilization in Year 1. However, the rationale supporting the 21% increase in volumes in mobile PET procedures from 475 procedures in Year 1 to 573 procedures in Year 2 remains somewhat unclear. Please also discuss the methodology used to project volumes in Year 2 in more detail.

The payer mix table supporting the projected utilization is noted. A comparison to previous mobile PET volumes performed during the September 2013 – February 2015 period would be appreciated. Please complete the table below.

Mobile PET Service Prior Payer Mix, September 2013 - February 2015

Payor Source	# of Mobile PET Scans Performed	PET Service Gross Revenue Amount	as a % of Total Gross Revenue
Medicare	65	298,582	42
TennCare	16	73,112	10
Managed care	37	168,674	24
Commercial	32	159,749	23
Self-Pay	1	5,200	1
Other	0	0	0
Total	151	705,317	100

**Response:** When the applicant was pulling the data for the above table, it discovered an error in the number of PET scans previously reported. Instead of 227 scans performed during the 17 months it operated the PET service, NorthCrest performed 151. The applicant anticipates replacing pages in the previous response to supplemental questions as well as the application itself to correct this error.

Based on the new numbers, the applicant is projecting 200 PET scans the first year of operation, increasing to 250 the second year of operation and 263 the third year of operation. The guidelines anticipate that an applicant will be able to perform 133 PET scans per day on a



Waller Jeff Grimm HSDA Examiner April 29, 2015 Page 3

> mobile scanner the first year of service, increasing to 320 PET scans the second year. NorthCrest is anticipating initially providing the service one half day a week, but needs the flexibility to be able to provide a 2<sup>nd</sup> half day when the number of scans ordered warrants it in order to better accommodate the needs of patients and their physicians. Therefore, it meets this standard. While it does not anticipate that it will meet the number of PET scans recommended for the 2<sup>nd</sup> year, the utilization it is proposing is certainly sufficient to justify at least the 2 half days initially requested. Given that NorthCrest performed 150 scans, or an average of about 4 scans per day, when it previously provided the mobile service, and given that the number of scans performed on Robertson County residents was 266 in 2013, the applicant feels that these numbers are conservative estimates of the number of PET procedures it will perform if the service is approved. The applicant anticipates that while the majority of the patients served will be Robertson County residents, they will also serve a significant number of Montgomery County and Cheatham County residents. According to the HSDA equipment registry, 241 Montgomery County patients and 156 Cheatham County patients utilized PET scan services outside of their respective counties. Since the NorthCrest location would be a more convenient location for many of these residents, some of them would likely be captured by the new PET service at NorthCrest should the requested CON be approved. Since NorthCrest is on the Kentucky border, patients from Kentucky utilize its medical services and would also be expected to utilize the PET services.

> The applicant feels that the longer it operates the PET service, the more likely it will be to capture more of the outmigration for PET. In addition, both Vanderbilt and Tennessee Oncology physicians currently order scans in Nashville. These two groups alone accounted for 154 PET scans for Robertson County residents. These doctors have indicated that the convenience and ease of the ability to access the PET services locally greatly enhance the patient care they can provide, and if the service were offered more than one day per week, they would utilize it more. In addition to its uses for cancer detection, the scanner is used by neurologists, pulmonologists, general surgeons and vascular surgeons. If this project is approved, it will decrease drive times, provide more convenient access, and offer expert local interpretation for speed of diagnosis. In particular, the age group that is the most likely to receive PET services, 65+, is growing in both the primary and secondary service areas. Therefore, some utilization is expected to come from this increase in population as well.

A review of other mobile PET providers throughout the state shows that PET services are currently being provided in 7 counties in which the population is less than the population of Robertson County: Coffee, Cumberland, Greene, Hamblen, McMinn, Obion, and Rhea. PET has become an essential tool in detecting cancer throughout the body. PET is able to diagnose disease before structural changes become detectable with anatomical imaging techniques, potentially improving the prognosis. The residents of Robertson County also deserve more convenient access to such an important diagnostic tool.



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#### 3. Section B, Project Description, Item II.E.

Item 2.a. and Item 2.b.

The sites served by the vendor's mobile PET unit during the previous 17 month period that the hospital provided the service are noted. In reviewing the proposed schedule for Thursday afternoon, Friday morning and potentially Monday morning days of operation, it appears that the distances to the Desoto Mississippi and Union City, Tennessee mobile PET sites may impact the ability to expand to more days at Northcrest. In addition to distance, what other factors must be taken into consideration to determine whether or not an additional mobile PET unit may be necessary in order to implement the schedule desired? If an additional unit is utilized, how might this be reflected in the contractual agreement between the hospital and the vendor? Please clarify.

Response: The applicant has been assured by the proposed vendor that the vendor will be able to accommodate its schedule and needs to provide PET services. It will be the vendor's decision to determine if an additional scanner is necessary to adequately meet the demands at NorthCrest. As such, any factors to be considered are not up to the applicant, but to the vendor. The use of an additional unit would not necessarily be reflected in the agreement between the hospital and the vendor, just as the previous agreement did not identify other sites of operation for the vendor.

#### 4. Section C. Need Item 1. (Project Specific Criteria – PET Service)

Item 4- The response is noted. With respect to the referral arrangements with Vanderbilt Ingram Cancer Center and Tennessee Oncology, the applicant states that these entities offer chemotherapy services on the Northcrest campus. Since chemotherapy utilization was not noted by the hospital in the most recent final 2013 JAR, please describe the arrangements between the parties and identify the most recent 12 month utilization that applies to this service at the hospital.

**Response:** As NorthCrest stated in response to question 4 in the previous request for supplemental information, many oncology services are provided through physician providers and not hospital providers. It is not NorthCrest that is providing the chemotherapy services so there is no utilization for NorthCrest to report on its JAR, and NorthCrest does not have access to the utilization for these other providers for chemotherapy services.

Item 6.c. – The "Emergency Spill Procedures" recently reviewed in April 2014 is noted. As an additional point of interest, please also briefly describe the responsibilities of the hospital's Radiation Safety Officer such as coordinating activities with first responders and providing notification to the appropriate state, local and federal emergency authorities.

**Response:** The Radiation Safety Officer will fulfill all obligations required under federal and state law, regulations and accrediting agencies. The RSO is responsible for coordinating all activities as they relate to the Emergency Spill Procedures, including obligations to coordinate all activities for spill management and clean up with first responders, and notifying the appropriate state, local and federal emergency authorities.

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#### 5. Section C, Need, Item 3 (Service Area)

The response is noted. The applicant has also clarified that the prior and future utilization of the mobile PET service will include use by residents of Montgomery and Cheatham Counties in Tennessee. As such, it would be helpful to illustrate historical PET utilization by residents of the Secondary Service Area in the table below.

PET Utilization by Residents of Applicant's Secondary Service Area

	2011	2012	2013
Cheatham County Resident Procedures at all TN Provider Sites	186	167	156
Montgomery County Resident Procedures at all TN Provider Sites	539	551	508
SSA Resident procedure Rate per 1,000 population	3.36	3.27	2.97

Sources: HSDA Equipment Registry, TDH population estimates

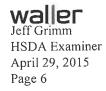
#### 6. Section C, Economic Feasibility, Item 4. (Projected Data Chart)

Per the response provided, thank you for clarifying that the audited Consolidated Statement of Operations contained in the attachments pertains to Northcrest Medical and Affiliates. Of the affiliates noted on page 6 of the Kraft CPA, LLC audited report, reference is made to Northcrest Health Network, LLC (NHN), a nonprofit physician hospital organization. Does the applicant have an ownership relationship with NHN that should be noted as a part of the application (Section A, Applicant Profile, Item 3)? If so, please discuss the proposed organizational and business relationships among these entities in such a manner that their affiliation with the project can be understood. An organization chart will be helpful.

Response: While NorthCrest Medical Center may have ownership interest in other entities, none of these ownership interests have any bearing on the request to initiate PET services or the provision of these services. The PET services, if approved, will be a part of the hospital and not any other entity. NorthCrest Medical Center is currently the sole member of NHN. NorthCrest Physician Services is a wholly owned subsidiary of NorthCrest Medical Center. This entity also is not related to the provision of the PET services by NorthCrest. An organizational chart is included as Attachment C, Economic Feasibility, Item 4.

#### 7. Section C., Economic Feasibility, Item 6 B.

The applicant's average charge of \$5,684.00 per PET procedure is different than the \$3,679 average gross charge identified on in the response to Item 5 on page 24 and the \$3,679 average gross charge derived from the Projected Data Chart on page 26 of the application. Please explain the differences between the amounts.



**Response:** The applicant responded to Question 12 of the previous supplemental questions that \$5,684 was the average charge for a PET procedure, according to the HSDA registry. That number is not related to the numbers for the applicant of \$3,679, so there is no difference between the amounts reported. As stated in the previous responses, when you compare the charge for NorthCrest for PET services with either the average charge, or the charges identified in the table below, NorthCrest's charges are closest to the charges identified for the first quartile, and are well below those for the median and the 3<sup>rd</sup> quartile.

In your response, please compare the correct charge to the range from the HSDA Equipment Registry shown below (as based on provider reports for CY 2013).

#### PET Average Gross Charge Range, CY 2013

1st Quartile	Median	3 <sup>rd</sup> Quartile
\$3,543.30	\$4,543.25	\$7,302.21

The applicant is including the following documents:

- Revised First Supplemental Responses, including a revised Project Cost Chart. There are no changes to the other attachments previously submitted.
- Revised Application Pages 9, 10, 12, 21, 23, 26 and 29

If you have any questions, please give me a call.

Sincerely,

Kim Harvey Looney

KHL:lg Enclosures

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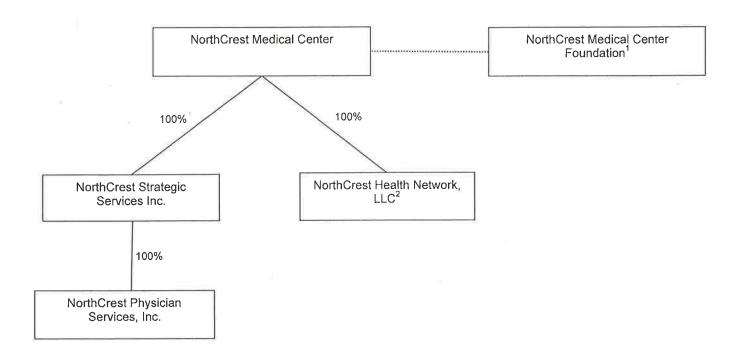
Second Supplemental Request

Attachment 6 - Economic Feasibility - Item 4 Organizational Chart

**April 29, 2015** 

Organizational Chart

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<sup>1.</sup> NorthCrest Medical Center Foundation is a NorthCrest Medical Center affiliate organized to foster, promote, develop and provide healthcare facilities in Robertson County.

2. NorthCrest Medical Center is the sole member of NorthCrest Health Network, LLC.

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**Second Supplemental Request** 

Revised First Supplemental Responses Originally Submitted April 22, 2015





Waller Lansden Dortch & Dav**April 29**15**2045** mair 511 Union Street, Suite 2700 P.O. Box 198966 3:04 pmallerlaw.com Nashville, TN 37219-8966

Kim Harvey Looney 615.850.8722 direct kim.looney@wallerlaw.com

April 29, 2015

#### VIA HAND DELIVERY

Jeff Grimm
HSDA Examiner
Tennessee Health Services and Development Agency
9<sup>th</sup> Floor
502 Deaderick Street
Nashville, TN 37243

Re: Revised First Supplemental Request for NorthCrest Medical Center CN1504-013 - Certificate of Need for Initiation of PET Service on Hospital Campus (originally submitted on April 22, 2015

Dear Jeff:

This letter is submitted as the supplemental response to your letter dated April 16, 2015, wherein additional information or clarification was requested regarding the above-referenced CON application.

#### 1. Section A, Applicant Profile, Item 9

Please provide a bed complement table for the response and submit as replacement page 4 of the application.

**Response:** See attached bed complement table included as <u>Attachment A-9</u>.

#### 2. Section B, Applicant profile, Item 13

An immediate benefit of the project appears to be participation in the hospital's PET service by members of Southern Radiology Associates. With respect to payment for services, review of Item 1.3.6 of the former contract between the applicant and the hospital appears to confirm coordination of insurance benefits between the parties pertaining to participation by SRA in Medicare, Medicaid and other insurance plans in which the hospital participates. Review of Item 1.9 reflects that SRA must accept assignment of Medicare and Medicaid benefits on all Medicare and Medicaid patients. Given the expiration of the former agreement on 2/1/2015 and no replacement documentation for same such as a draft working agreement between the parties, please describe the arrangement planned for the proposed service. Will the hospital bill on a global basis, collect payments for services and reimburse the SRA radiologists on some prearranged basis? If billing separately, it would be helpful to include names, medical and provider license numbers of the SRA radiologists involved in this regard.

Response: It is anticipated that a contract that is substantially similar to the previous contract for SRA will be used should this PET service be approved, and it has been included for purposes of a draft agreement. The purpose of the contract is to ensure that the professional portion of the PET service is

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covered, including any supervision, if necessary. The previous contract includes an auto-renewal provision, so technically it is an ongoing agreement. The hospital will not bill globally, but only for the technical component. The radiologists will be responsible for billing and collecting for the professional services provided. A list of the radiologists for SRA is included below, along with the medical provider license numbers. Any of these radiologists might be responsible for the professional component for these proposed PET services. W. Wesley Brewer, M.D. will serve as the Medical Director.

List of Radiologists	<u>License</u>
Nathan R. Berkley, MD	39255
Brice T. Boughner, MD	44452
W. Wesley Brewer, MD	40361
James B. Butler, MD	21236
Gregory M Galdino, MD	42217
Daniel Grippo, MD	39219
James Grippo, MD	41992
Josh M. Heck, MD	49141
Robert J Mahoney, MD	35641
Joseph E. Pate, MD	26817
Gary T Podgorski, MD	15386
Michael S. Rissing, MD	51888
David M. Shackelford, MD	41711
Matthew Stephenson, MD	49955

#### 3. Section B, Project Description, Item I

The executive summary is noted. Please provide brief remarks that identify the ownership structure, the need for the mobile service based on the extent of resident outmigration for PET services at other provider locations, and a brief description of the financial performance of the project in terms of sustainability of the service in light of the hospital's unfavorable net operating income reflected in the Historical Data Chart and audited financial statements (Statement of Operations) provided in the application.

Response: The PET service will be provided as an outpatient service of the hospital so there is no separate ownership structure for the service itself. The PET service is anticipated to generate positive revenue. As a rural non-profit acute care provider, NorthCrest has been working very hard to reverse a decline in the financial performance of the hospital. Since 2013, as is shown in its financial statements, NorthCrest has made positive strides in reducing the decline in operating income, partly by working to cut its expenses. The prior decline in operating income in 2013 was significantly decreased in 2014 and again year to date 2015. NorthCrest has also been evaluating the services it provides and seeking to strengthen its outpatient services. The ability to add PET services to the array of outpatient services offered will assist patients in receiving quality care close to home, as well as allow NorthCrest to continue

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to increase the outpatient services it provides, which will help alleviate the financial burden on a sole community, rural, non-profit hospital provider. The patients who reside in Robertson County and the surrounding areas want to receive their health care services in their communities; they do not want to come to an unfamiliar place like Nashville to receive medical services. To do so is confusing and more time consuming than receiving the services locally.

Because the service is not currently provided in Robertson County, providers ordering PET scans must refer patients to other counties for PET services. According to the HSDA Equipment Registry, the top 3 providers for PET scans by Robertson County residents are Imaging Alliance, Tennessee Oncology, and VUMC, all located in Davidson County. In 2013, according to the HSDA Equipment Registry, these 3 providers collectively performed 248 scans, or 93% of the total scans for Robertson County residents.

Please explain in more detail why the hospital and the equipment vendor did not know that PET was a reviewable Certificate of Need service immediately prior to or during the 17 months the mobile PET service was operated at NorthCrest Medical Center.

Response: There was some confusion as to whether or not a CON was required to initiate PET services, and which entity was the entity that needed to have the CON to provide PET services. NorthCrest did not realize it had to be the entity to receive a CON to provide PET services. When Alliance added NorthCrest to its radiopharmaceuticals license with the State of Tennessee, NorthCrest was under the impression that was the only approval that was necessary for it to begin providing PET services. NorthCrest thought it was covered under the mobile provider, but was under the impression that if it were to implement the service on a fixed basis, it would have to have its own CON. The error was discovered in the process of researching the requirements to have fixed PET services. At that time, NorthCrest immediately discontinued the service and made plans to file a CON to initiate the PET service. All of the PET scans that were performed received prior approval from the payers, including Medicare and TennCare.

# 4. Section B, Project Description, Item II.C

The applicant states that the oncology services provided to residents of Robertson County have increased in recent years. However, review of the hospital's 2013 Joint Annual Report (JAR) revealed that the hospital did not provide chemotherapy services or radiation therapy services during the period. Additionally, surgery volumes related to cancer cannot be determined from the JAR. As such, additional description of the hospital's cancer program is needed. Please address the following items:

A) The incidence of cancer in Robertson County compared to statewide rates using information available through the Tennessee Department of Health,

**Response:** According to the report, Cancer in Tennessee 2006-2010, published in 2013 by the Tennessee Department of Health, the incidence of cancer in Robertson County was 494.9 per 100,000, which is 3.1% higher than the overall Tennessee rate of 479.9 per 100,000.

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B) The nature and scope of the hospital's existing cancer programs through its participation in the Vanderbilt Health Affiliate Network (VHAN),

Response: Many of the oncology services in an area are offered through physician providers and not hospital providers. Participation in VHAN has brought three (3) additional medical oncologists to Robertson County to provide services, and the Vanderbilt Ingram Cancer Center provides chemotherapy on NorthCrest's campus, thereby increasing access to oncology services for the service area residents. Tennessee Oncology also provides chemotherapy services to its patients in its space on the NorthCrest campus. PET is currently the only diagnostic service for cancer that is currently not provided on NorthCrest's medical campus.

C) A description of the hospital/medical staff organizational structure for coordinating the activities of the oncology program,

**Response:** All medical staff involved in the cancer program participate in the tumor board to discuss incidence, types, treatments and outcomes of cancers. In general, the medical oncology services provided by the particular oncology providers are directed by their practices and not the hospital. Each practice is responsible for the medical care of their patients.

D) A description of the hospital's tumor registry and tumor board and information systems support for these activities, and

**Response:** NorthCrest Medical Center utilizes a contracted tumor registrar to complete all reporting to the Tennessee Cancer Registry.

Tumor Board – Dr. Anjali Sibley directs the tumor board at NorthCrest Medical Center which assembles monthly for tumor conference. All health information systems utilized at NorthCrest are utilized collaboratively as applicable to support both Tennessee Cancer Registry reporting and tumor board activities.

E) A description of how the proposed PET service can contribute to any clinical investigative protocols through formal oncology network relationships with other providers.

**Response:** This proposal will allow NorthCrest, through its formal relationships with the Vanderbilt Ingram Cancer Center, and Tennessee Oncology to participate in clinical trials. PET is currently the one diagnostic tool that is missing for oncology services at NorthCrest.

Positron emission tomography (PET) has become an essential tool in detecting cancer throughout the body. A PET scan is very different from an ultrasound, X-ray, MRI, or CT. Unlike these imaging technologies which merely confirm the presence of a mass, a PET scan can distinguish between benign and malignant disorders. A PET scan can detect abnormalities in cellular activity, generally before there is any anatomical change. PET is able to diagnose disease before structural changes become detectable with anatomical imaging techniques, potentially improving the prognosis. PET scans allow doctors to

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detect abnormalities in glucose metabolism, which is a hallmark of cancer cells. PET scans assist in the diagnosis and staging of cancer. PET helps avoid the expense and pain of removing benign nodules, as well as invasive biopsy procedures to determine malignancy. Reports in the scientific literature find that, in some tumors, PET correctly identifies detected lesions 95% of the time. Because PET can survey the whole body, PET can identify distant, occult metastases that may affect the course of treatment and therefore change patient management. PET scans can also be used to determine if treatment has destroyed all of a patient's cancer.

The applicant states that the previous service averaged approximately 8 PET procedures per month from September 2013 through February 2015. At that rate, it appears that approximately 136 PET procedures were performed during the 17 month period in lieu of the 227 procedures (average of 13 per month) indicated in your response on page 9 of the application. Please clarify.

**Response:** The applicant previously incorrectly identified the average PET procedures per month. The applicant discovered some duplicative counts in the PET numbers provided. The average was 9 PET procedures per month and the total procedures were 151 for the 17 month time period.

Review of HSDA Equipment Registry records revealed that residents of Robertson County had approximately 266 PET procedures at Tennessee provider locations in calendar year (CY) 2013, excluding PET utilization of Robertson County residents at Northcrest during the 12-month period. Assuming residents of the county had approximately 100 scans at Northcrest in CY2013 (8 per month x 12 months), it would appear that the residents had approximately 366 PET procedures in 2013. With this in mind, the applicant's projections for 475 PET procedures in Year 1 (2015) increasing by 21% to 573 procedures in Year 2 appear to exceed resident demand for the service. Please explain how utilization by residents of the county can support the projected volumes identified for the proposed 2-3 day per week mobile service.

Response: If NorthCrest has the flexibility to offer the service one day per week, but does so on two different half days per week, the physicians who order the scans are anticipated to order more locally, as that is the best option for the provision of this important diagnostic tool. Letters from area physicians supporting the implementation of this services are included.

The applicant states in the application that the majority of the patients are expected to come from Robertson County residents. That does not mean that only patients from Robertson County will utilize the service. Perhaps a better way to describe the service area is to identify Robertson County as the primary service area, with a secondary service area of Cheatham and Montgomery Counties. In addition, as NorthCrest is on the Kentucky border, patients from Kentucky also utilize the medical services it offers, and are anticipated to use the PET services.

NorthCrest reviewed the utilization of the PET services and determined that while 76% of the services provided were for Robertson County residents, 24% of the utilization was in secondary markets outside of Robertson County. The referring physicians have requested that the PET service be provided on two half days per week in order to best meet the needs of service area residents, family members and physicians.

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After NorthCrest adjusts for the duplicative numbers, it anticipates that 200 scans will be performed the first year, increasing to 250 the second year and 263 the third year of operation. NorthCrest based its projection of 200 scans in year one from the following geographic areas:

%/Number	State / County	
5/10	Kentucky	
5/10	Cheatham	
10/20	Montgomery	
2/4	Sumner	
2/4	Davidson	
76/152	Robertson	

Cheatham and Montgomery Counties are the two Tennessee counties comprising the majority of the secondary service area. According to the HSDA equipment registry data for 2013, 241 Montgomery County patients and 156 Cheatham County patients utilized PET scan services outside of their respective counties. These patients who received PET services outside of their resident counties traveled to virtually the same PET service locations as the Robertson County residents. Since the NorthCrest location would be a more convenient location for many of these patients, as outlined above, some of them would likely be captured by the new PET service at NorthCrest should the requested CON be approved. Below is the population data for the two counties comprising the majority of the secondary service area, Cheatham and Montgomery:

#### Secondary Service Area

Cheatham County					
Age	2015	2019	% Change		
0 to 19	9,975	8,517	(14.6)		
20 to 44	10,916	10,103	(7.4)		
45 to 64	14,082	16,269	15.5		
65 to 74	3,743	4,713	25.9		
75 plus	1,372	1,363	(.66)		
Total 65 plus	5,115	6,076	18.8		
Total	40,088	40,965	2.2		

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<b>Montgomery County</b>					
Age	2015	2019	% Change		
0 to 19	61,953	67,744	9.3		
20 to 44	71,655	71,626	(.04)		
45 to 64	40,491	44,331	9.5		
65 to 74	10,414	12,310	18.2		
75 plus	6,555	7,449	13.6		
Total 65 plus	16,969	19,759	16.4		
Total	191,068	203,460	6.5		

Total Secondary Service Area					
Age	2015	2019	% Change		
0 to 19	71,928	76,261	6.0		
20 to 44	82,571	81,729	(1.0)		
45 to 64	54,573	60,600	11.0		
65 to 74	14,157	17,023	20.2		
75 plus	7,927	8,812	11.2		
Total 65 plus	22,084	25,835	17.0		
Total	231,156	244,425	5.7		

As is shown in the population charts above, and in the charts in the application, the population aged 65 and older is expected to increase significantly between 2015 and 2019, for both the primary and secondary service areas, well over the increase for the total population in these counties. It is the 65+ age group which is expected to be the highest users of PET services.

#### 5. Section B, Project Description, Item II.E.

<u>Item 2.a</u> – Please provide the name of the unit, year manufactured, and date acquired by the vendor. Excluding downtime for maintenance, how long has the mobile unit been in use?

Response: The mobile unit is a PET/CT 119, manufactured in 2006, and was acquired December 1, 2008, by the mobile vendor, and has been in continuous use since that time.

Please identify all existing sites of the proposed mobile unit, distance from the applicant and days of week they are scheduled.

Response: It is the applicant's understanding that the mobile vendor provided services to the following providers with the same PET/CT scanner, during the time NorthCrest first initiated the service. These routes may be adjusted and/or an additional scanner used to provide services to NorthCrest for its proposed Thursday operation and potentially Friday and Monday operation. NorthCrest proposes to offer the services on a convenient schedule for patients. The more different days on which it can offer the

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services, the more of the outmigration it should be able to capture. Since none of the proposed days are full days, the applicant is proposing services initially for one half day per week increasing up to a total of 3 half days per week. The applicant proposed Tuesday and Thursday mornings for initial times of operation in the application, but has since revised the proposed schedule to Thursday afternoon, Friday morning if necessary, and potentially Monday morning, should it be needed, after further discussions with the mobile vendor.

Williamson Medical Center: Franklin, TN - Monday - 50 miles

Maury Regional: Columbia, TN - Monday - 50 miles

BMH- Desoto; Southhaven, MS - every other week - Wed, Thurs - 250 miles

BMH- Union City: Union City, TN - Friday - 170 miles

Harton Regional: Tullahoma, TN – First Sat. of every month, and the following 2 weeks on Wed – 100 miles.

<u>Item 2.b</u> – the applicant states that the service may be provided up to 3 days per week to meet the needs of service area residents. Please explain why this is necessary when the prior service operated 1 day per week over the 17 months ending February 2015.

**Response:** NorthCrest anticipates providing the service initially one half day per week, with the flexibility to offer the service on a second half day as needed to service the needs of the residents of Robertson County and surrounding areas to provide convenient access to those patients who find unnecessary travel a hardship and prefer to obtain a PET scan locally, and with minimal travel time. If utilization warrants an increase in the amount of time the service is offered, NorthCrest would like to be able to offer up to 3 half days per week to meet those needs. As stated previously there is no PET service provider within approximately 30 miles of NorthCrest Medical Center.

The referring physicians in the area feel it is necessary to have the flexibility to provide the PET service on more than one half day per week in order that patients in Robertson County may receive the service as close to home as possible, in the least restrictive setting. The ability to receive the service in Robertson County means less disruption to both the patient's work schedule as well as any family members who are assisting in the receipt of medical services by the patient. NorthCrest is proposing to provide the service initially one half day per week, with the flexibility to provide additional half days as necessary.

The CON application proposed that the PET services be provided on Tuesday and Thursday mornings. After further discussions with the equipment vendor, NorthCrest has adjusted the schedule of operations and anticipates providing the services initially on Thursday afternoon with the flexibility to also offer on Friday morning for half a day, and when justified, expanding the service an additional half day a week to Monday. That way, the mobile scanner does not have to be moved during the week to go and come back to NorthCrest, but is on a less disruptive schedule for the mobile vendor.

<u>Item 2.c</u> – The applicant states that the cost of the lease has not yet been determined. At a minimum, documentation of the equipment lease should be provided in the form of a Letter of Intent between the hospital and the equipment vendor in lieu of the expired lease agreement used for the previous

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arrangement. Please clarify by providing the documentation requested to support the Project Cost of the application.

**Response:** Please see <u>Attachment 5.B-Item II.E.(2c)</u> lease for the equipment. The equipment vendor has structured it as an amendment to the original lease, which has an evergreen clause. The applicant anticipates that the amount of the lease will be the same as during the time it was previously performing the service and has included that amount - or \$3,090 per day of service - in it projected costs.

Who does the equipment vendor use to obtain the FDG/radioactive material at the cost of \$150 per dose? Please provide the name of the supplier and address. Please also identify the distance to the closest cyclotron source. Are these costs reflected in the Project Cost Chart on page 20?

Response: NorthCrest anticipates that the mobile provider will receive the radiopharmaceuticals from the Vanderbilt entity identified below, which is approximately 30 miles away. The costs for the dose are included in the Projected Cost Chart in Other Supplies. A revised Project Cost Chart has been included as Attachment 5-Item II.E2(c) to identify these other supplies as the radiopharmaceuticals.

PETNET – Vanderbilt MRB, Room 1251 2222 Pierce Avenue Nashville, TN 37232-6315

<u>Item 2.d</u> - Please provide documentation from the equipment vendor that describes how the \$225,000 fair market value estimate of the mobile unit was determined.

Response: Please see Attachment 5.B-Item II.E.(2d) letter identifying the FMV of the mobile unit at \$225,000.

#### 6. Section C. Need Item 1. (Project Specific Criteria – PET Service)

Item 1 -Patients with cancer diagnoses appear to account for approximately 78% of the 475 projected PET procedures shown in the table on page 12 for Year 1. Please include the cancer incidence rate of Robertson County residents for the most recent period available in documentation in information maintained by the Department of Health or other sources of population data.

**Response:** According to the report, Cancer in Tennessee 2006-2010 published in 2013 by the Tennessee Department of Health, the incidence of cancer in Robertson County was 494.9 per 100,000, which is 3.0% higher than the overall Tennessee rate of 479.9 per 100,000.

As noted, please justify the increase in PET procedures at the amounts indicated in light of both the applicant's prior utilization and resident PET procedures. For resident PET procedures, please show for 2011 – 2013 by contacting Alecia Craighead, Stat III, HSDA.

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Response: The applicant states in the application that the majority of the patients are expected to come from Robertson County residents. That does not mean that only patients from Robertson County will utilize the service. Perhaps a better way to describe the service area is to identify Robertson County as the primary service area, with a secondary service area of Cheatham and Montgomery Counties. In addition, as NorthCrest is on the Kentucky border, patients from Kentucky also utilize the medical services it offers, and are expected to utilize the PET services.

NorthCrest reviewed the utilization of the PET services and determined that while 76% of the services provided were for Robertson County residents, 24% of the utilization was in secondary markets outside of Robertson County. The referring physicians have requested an additional day for the PET service, and NorthCrest requests the ability to do so as utilization warrants.

NorthCrest based its projection of 200 scans in year one from the following geographic areas:

%/Number	State / County
5/10	Kentucky
5/10	Cheatham
10/20	Montgomery
2/4	Sumner
2/4	Davidson
76/152	Robertson

Cheatham and Montgomery Counties are the two Tennessee counties comprising the majority of the secondary service area. According to the HSDA equipment registry data for 2013, 241 Montgomery County patients and 156 Cheatham County patients utilized PET scan services outside of their respective counties. These patients who received PET services outside of their resident counties traveled to virtually the same PET service locations as the Robertson County residents. Since the NorthCrest location would be a more convenient location for many of these patients, as outlined above, some of them would likely be captured by the new PET service at NorthCrest should the requested CON be approved.

Below is a chart with data from the HSDA showing the Robertson County resident PET procedures for 2011-2013:

	2011	2012	2013	
Robertson County Resident Procedures at all TN Provider	314	279	266	
Sites				
Total Resident PET Procedure	4.68	4.09	3.84	
Rate per 1,000 population	1,00	1.07		
Statewide PET Rate per 1,000 population	4.64	4.60	4.30	

HSDA Equipment Registry, TDH population estimates

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Item 4- The referral arrangements with Vanderbilt Ingram Cancer Center and Tennessee Oncology are noted. Given the absence of chemotherapy services and radiation therapy services at Northcrest, what arrangements are planned for referrals to other facilities in contiguous counties such as Davidson County? As part of same, what assurances will be provided for acceptance of PET scans performed by the applicant? Under what circumstances will rescanning be necessary?

Response: NorthCrest offers medical and surgical oncology services on-site through its relationship with Vanderbilt Ingram Cancer Center and Tennessee Oncology. Additionally its medical staff have existing referral relationships with regional medical centers for oncology care. Both the Vanderbilt Ingram Cancer Center and Tennessee Oncology, offer chemotherapy services on the NorthCrest Medical Center campus. The closest radiation therapy services are provided by these providers in either Clarksville or Nashville. NorthCrest does not anticipate that rescanning for PET services will be necessary as the scans will be ordered by the providers who will be using them. Of course, during the course of treatment, additional scans may be ordered to track the effectiveness of treatment.

Item 6.c. – Please also address the hospital's procedures to be implemented in the event of a spill of the radioactive material used for the mobile PET unit. What are the responsibilities of the medical director or appropriate hospital personnel for same?

Response: Please see <u>Attachment C-Need-Item6(c)</u> Hospital policy. NorthCrest will provide physician supervision for the PET/CT service, with radiologist interpretation onsite provided by SRA. Alliance will provide a PET Certified Nuclear Medicine Technologist as part of the provision of the PET scanner.

Item 6.f.-it appears that the response would include comment about SRA physicians being active members of the hospital medical staff. Please clarify.

**Response:** The Medical Director, as well as all SRA physicians, are credentialed as active members of NorthCrest Medical Center's medical staff.

Item 8.b – please include comment here about findings of the cancer incident rate for residents of Robertson County. Please also compare to the statewide average rate for the most recent 12 month period available.

**Response:** According to the report, Cancer in Tennessee 2006-2010 published in 2013 by the Tennessee Department of Health, the incidence of cancer in Robertson County was 494.9 per 100,000, which is 3% higher than the overall Tennessee rate of 479.9 per 100,000. In addition, the mortality rate in Robertson County is 210.5, which is 6% higher than the overall Tennessee rate of 198.2.

#### 7. Section C, Need, Item 3 (Service Area)

Please complete the table below documenting resident PET utilization:



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	2011	2012	2013
Robertson County Resident Procedures at all TN Provider Sites	314	279	266
Total Resident PET Procedure Rate per 1,000 population	4.68	4.09	3.84
Statewide PET Rate per 1,000 population	4.64	4.60	4.30

HSDA Equipment Registry, TDH population estimates

As noted elsewhere, the data reported to the HSDA Equipment Registry does not include utilization for PET procedures performed at NorthCrest.

### 8. Section C, Need, Item 5

The absence of other PET providers in Robertson County is noted. Please identify the use of PET providers in Davidson County and other areas of TN by residents of Robertson County for the most recent 3 years. A suggested template is provided in the table below. Please contact Alecia Craighead, HSDA Stat III for assistance with data from the HSDA Equipment Registry.

PET Utilization by Robertson County Residents, 2011-2013

Providers with PET Service	Provider Location	Distance from Applicant (Miles)	2011	2012	2013	% Change '11-'13
Premier	Davidson	32.1	0	0	10	0.0%
Imaging Alliance	Davidson	31.4	86	118	94	9.3%
TN Oncology	Davidson	32.0	130	88	89	(31.5%)
Centennial	Davidson	33.8	10	10	5	(50.0%)
VUMC	Davidson	32.9	42	58	65	54.76%
St. Thomas Midtown	Davidson	27.5	36	0	0	(100.0%)
Subtotal-Davidson County			304	274	263	(13.5%)
Gateway Medical Center	Montgomery	32.9	6	4	3	(50.0%)
Tennessee PET Scan Center	Rutherford	55.1	2	0	0	(100.0%)
East Memphis PET Imaging Center, LLC	Shelby	227	2	1	0	(100.0%)
All other TN providers			10	5	3	(70.0%)
Total -TN			314	279	266	(15.3%)

<sup>•</sup>Note: new provider Source: HSDA Equipment Registry, 2013 Service Utilization Records

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### 9. Section C, Need. Item 6 (applicant's projected Utilization)

It appears that the applicant is projecting utilization in Year 1 that amounts to approximately 130% of the total estimated utilization of Robertson County residents in 2013. Please explain how this is possible by explaining the methodology that was used to project PET volumes of the project in more detail.

Response: Please note that the number of scans previously reported in the application and the supplemental responses was incorrect. The average number of scans performed per month at NorthCrest was 9, rather than the 8 reported in the original application. Projected utilization is no longer at 130% of the Robertson County residents in 2013. If NorthCrest offers the service on more than one half day during the week, the physicians who order the scans are anticipated to order more locally, as that is the best option for the provision of this important diagnostic tool.

The applicant states in the application that the majority of the patients are expected to come from Robertson County residents. That does not mean that only patients from Robertson County will utilize the service. Perhaps a better way to describe the service area is to identify Robertson County as the primary service area, with a secondary service area of Cheatham and Montgomery Counties. In addition, as NorthCrest is on the Kentucky border, patients from Kentucky also utilize the medical services it offers, and are expected to use the PET services.

NorthCrest reviewed the utilization of the PET services and determined that while 76% of the services provided were for Robertson County residents, 24% of the utilization was in secondary markets outside of Robertson County. The referring physicians have requested an additional day for the PET service.

NorthCrest based its projection of 200 scans in year one from the following geographic areas:

%/Number	State / County
5/10	Kentucky
5/10	Cheatham
10/20	Montgomery
2/4	Sumner
2/4	Davidson
76/152	Robertson

Cheatham and Montgomery Counties are the two Tennessee counties comprising the majority of the secondary service area. According to the HSDA equipment registry data for 2013, 241 Montgomery County patients and 156 Cheatham County patients utilized PET scan services outside of their respective counties. These patients who received PET services outside of there resident counties traveled to virtually the same PET service locations as the Robertson County residents. Since the NorthCrest location would be a more convenient location for many of these patients, as it is located between I-65 and I-24, some of

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them would likely be captured by the new PET service at NorthCrest should the requested CON be approved.

In your response, please summarize the strategies that NorthCrest would need to implement to capture all outmigration of residents to providers outside the county. What are the key factors that will determine whether or not the capture rate methodology is attainable?

Response: Accessibility and ease of use is the key to capturing the majority of Robertson County. A large portion of the existing outmigration is primarily due to the existing physicians, primarily those from Vanderbilt and Tennessee Oncology ordering scans in Nashville. These two groups alone accounted for 154 scans for Robertson County residents. If some of this outmigration is halted, NorthCrest can easily justify the number of PET scans it has proposed. These doctors have indicated that the convenience and ease of the ability to access the PET services locally greatly enhance the patient care they can provide and if the service were offered more than one day per week, they would utilize it more, because any delay in treatment would be minimized.

Please show the percentages by payor for the proposed service in Year 1 of the project by completing the table below.

Payor Source	Year 1 Gross Revenue (as a % of total)	Average Gross Charge per PET procedure	Year 1 Gross Revenue (as a % of total)
Medicare	43	3,679	316,394
TennCare	12	3,679	88,296
Managed care	14	3,679	103,012
Commercial	23	3,679	169,234
Self-Pay	1	3,679	7,358
Other	7	3,679	51,506
Total	100	3,679	735,800

Mobile PET Service Payor Mix, Year 1

### 10. Section C, Economic Feasibility Item 1 (Project Costs Chart)

The following definition regarding major medical equipment cost in Tennessee Health Services and Development Agency Rule 0720-9-.01 (13)(b) states "The cost of major medical equipment includes all costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: (1) maintenance agreements, covering the expected useful life of the equipment; (2) federal, state, and local taxes and other government assessments and (3) installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding."

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Is the \$321,360.00 mobile PET unit equipment cost listed in Line A.7 of the Project Cost Chart consistent with the Rule? In your response, please provide a breakout of the key cost items of the fixed unit that apply to the project per Agency Rule above. If not, please make the necessary equipment cost adjustments and submit a revised Project Cost Chart.

**Response:** The unit is not a fixed unit but a leased mobile unit. The only costs associated are the day rental of the unit and the cost of radiopharmaceuticals. Any costs for maintenance are the responsibility of the mobile vendor. There are no renovations or capital expenses needed as unit is mobile and not fixed. Any costs listed are consistent with the appropriate rule.

### 11. Section C, Economic Feasibility, Item 4. (Projected Data Chart)

Line D.9 "Other Expenses" appears to be missing the anticipated mobile equipment lease cost with related costs for FDG, and expenses for contract fees with Southern Radiology Associates and/or related professional fees of the radiologists. Please identify same and provide a revised chart in a replacement page for the application labeled 26-R.

Response: The mobile rental rate is included under the Operating expense section under the Rental expense detail line, with an amount of \$154,500 (\$3,090 x 1 days x 50 weeks).

There are no additional fees paid to SRA; SRA bills and collects for the professional services it provides. The only fees payable to Alliance are the daily rate, plus the cost of the per patient PDG injection. A revised Projected Data Chart is not necessary.

Review of the Consolidated Statement of Operations in the attachments revealed differences in the entries for net operating revenue and net operating income from the amounts shown in the Historical Data Chart on page 25. As a result, it appears that the unfavorable net income may be higher than shown in the chart. Please clarify.

**Response:** The historical data chart provides information for the hospital only and not the consolidated information for all related entities. Both data sets are correct; they are just not the same.

### 12. Section C., Economic Feasibility, Item 6 B.

Please include a comparison to HSDA Equipment Registry PET charges in the response.

**Response:** According to the HSDA PET equipment registry for 2013, the average charge for a mobile PET procedure is \$5,684 per procedure. NorthCrest's proposed charges are on the low side of these charges.

What are the arrangements for professional fees related to imaging interpretation services by radiologists? Are these reflected in the Projected Data Chart for the mobile service?

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**Response:** SRA bills the professional component to each payer directly, and NorthCrest bills the technical component. There are no additional fees paid to SRA for this service and therefore no associated costs in the Projected Data Chart.

### 13. Section C, Economic Feasibility, Item 11 b.

A key benefit of the proposed service appears to be a more convenient and accessible site for residents of the county. Looking at distance/travel times as a key factor, what are the savings in mileage/driving times to the applicant's campus that residents of the service area could expect?

**Response**: Assuming an average of 30 miles to the next nearest PET or 60 miles round trip at \$.575 per mile, then the average Robertson County patient is saving \$34.50 per trip. In the consideration of time and aggravation, the average trip to Nashville (factoring traffic and construction delays) is twice to three times as long as the drive to NorthCrest. This is regardless of the location of the patient, from either the primary service area or the secondary service areas. Considering the average age of the patient, which is 65+, the drive is an important factor for ease of use.

What other key benefits should residents and their attending physicians be aware of in selecting NorthCrest's proposed PET service in lieu of other sites outside the service area?

Response: There are no existing providers of PET services in Robertson County. PET services are an essential tool in detecting cancer throughout the body. Unlike other imaging technologies which merely confirm the presence of a mass, a PET scan can distinguish between benign and malignant disorders. PET helps avoid the expense and pain of removing benign nodules, as well as invasive biopsy procedures to determine malignancy. The initiation of this service in Robertson County will allow more timely access to a necessary diagnostic tool and increase outcomes for its service area residents. In addition to its uses for cancer detection, the scanner is used by neurologists, pulmonologists, general surgeons, and vascular surgeons.

If this project is approved it will decrease drive times, provide more convenient access, and offer expert local interpretation for speed of diagnosis. If approved this project will significantly increase accessibility for local patients needing to obtain PET/CT examinations close to home.

The oncologists and other physicians providing services in Robertson County have indicated that they would prefer to send their patients to a location in Robertson County to receive PET services and the initiation of this service and the flexibility to offer it two half days a week will allow them to do so for most patients, without unduly delaying diagnosis and treatment of those patients.

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### 14. Section C, Orderly Development, Item 4

It is understood technical staff will be provided by the equipment vendor. However, please show by position classification.

**Response:** The professional staff provided by the mobile vendor will include either a certified nuclear medical technologist (CNMT) or an American Registry of Radiologic Technologists - Nuclear Medicine. (ARRT RT (N)).

### 15. Published Letter of Intent (LOI)

The LOI did not identify or otherwise specify the anticipated schedule such as number of days per week that the mobile PET service would be available at Northcrest. Please clarify why this information was omitted.

**Response:** NorthCrest Medical Center apologizes for inadvertently omitting this information from the LOI.

NorthCrest respectfully requests two half days of service, with the ability to increase to three half days when utilization so warrants. The current plan would be to initially provide one half day of service on Thursday afternoon from 1-5 p.m., with the flexibility to provide the service on Friday from 7:30-11:30 a.m., increasing to add Monday 7:30-11:30 a.m., as necessary. (The applicant initially proposed Tuesday and Thursday mornings, but upon further discussions with the mobile vendor, it has determined that this revised schedule will be better.) The unit will remain in service as long as required to serve patients needing service those particular days.

If you have any questions, please feel free to give me a call.

Sincerely,

Kim Harvey Looney

KHL:lag Encl.

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Attachment 5-Item II.E2(c) Revised Project Costs Chart

# April 29, 2015 3:04 pm

# PROJECT COSTS CHART

Α.	Cons	struction and equipment acquired by purchase:	Y
	1.	Architectural and Engineering Fees	0
	2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	\$35,000
	3.	Acquisition of Site	0
	4.	Preparation of Site	0
	5.	Construction Costs	0
	6.	Contingency Fund	0
	7.	Fixed Equipment (Not included in Construction Contract)	0
	8.	Moveable Equipment (List all equipment over \$50,000)	0 **
	9.	Other (Specify)	0
В.	Acqı	uisition by gift, donation, or lease:	*
	1,.	Facility (inclusive of building and land)	0
	2.	Building only	0
	3.	Land only	0
	4.	Equipment (Specify) Mobile PET Unit	\$321,360
	5.	Other (Specify) Supplies - Radiopharmaceuticals	\$71,250
C.	Fina	incing Costs and Fees:	
	1.	Interim Financing	0
	2.	Underwriting Costs	0
	3.	Reserve for One Year's Debt Service	0
	4.	Other (Specify)	0
D.	Esti	mated Project Cost (A+B+C)	\$427,610
E.	CON	N Filing Fee	\$3,000
F <sub>seo</sub>	Tota (D+l	al Estimated Project Cost E) TOTAL	\$430,610

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Second Supplemental Request

**Corrected Pages to Application Filed 4-13-15** 

# April 29, 2015 3:04 pm

proper CON approval, but discontinued those services as soon as it realized its error. During the time period that NorthCrest was providing PET services through a mobile PET/CT scanner, from September 2013 to 2015, 151 scans were performed, with an average of 9 per month. The flexibility to offer an additional second half day of operation per week will greatly increase access to and use of the PET scanner, according to area referring physicians.

The PET/CT scanner is a good option because in addition to having CT and PET stand-alone capabilities, it uses the CT images to correct for non-uniform attenuation of the PET images and it uses integrated CT and PET images to localize emission activity in the patient anatomy. The PET/CT scanner has capabilities for imaging all available PET tracers and CT contrast agents and can provide inherently registered anatomical and functional information via an integrated user interface.

As reimbursement has changed and lengths of stay for inpatient services have decreased in recent years, the inpatient services provided by NorthCrest have decreased or remained flat. In order for NorthCrest to remain financially viable it has worked hard to reduce its expenses and to increase the services provided on an outpatient basis. The ability to add PET services to the array of outpatient services offered will assist patients in receiving quality care close to home, as well as allow NorthCrest to continue to increase the outpatient services it provides, which will help alleviate the financial burden on a sole community, rural, non-profit hospital provider.

D. Describe the need to change location or replace an existing facility.

Response: Not applicable.

- Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:
  - 1. For fixed-site major medical equipment (not replacing existing equipment):
    - a. Describe the new equipment, including:
      - 1. Total cost ;(As defined by Agency Rule).
      - 2. Expected useful life;
      - 3. List of clinical applications to be provided; and
      - 4. Documentation of FDA approval.

Response: Not applicable.

b. Provide current and proposed schedules of operations.

Response: Not applicable.

- 2. For mobile major medical equipment:
  - a. List all sites that will be served;
  - Provide current and/or proposed schedule of operations;
  - c. Provide the lease or contract cost.

- d. Provide the fair market value of the equipment; and
- e. List the owner for the equipment.

Response: The applicant proposes to lease a mobile PET/CT scanner to operate at its hospital location. The applicant proposes to provide the service up to three (3) half days per week in order to meet the needs of service area residents. The schedule of operation is anticipated to be one (1) half day per week when the service is implemented - on Thursday afternoon from 1:00 p.m. to 5:00 p.m. with the flexibility to add Friday morning from 7:30 a.m. to 12:30 p.m., and if warranted to expand to add a 3<sup>rd</sup> half day on Monday morning. The cost of the lease has not yet been determined. In both the Project Costs Chart and the Projected Data Chart, the applicant used \$3,090 per five (5) hour half day of service with an hourly overtime rate of \$300 per hour and a charge of \$150 per radiopharmaceutical dose. The fair market value of the equipment is \$225,000. The owner of the equipment is Alliance Healthcare Services, Inc. ("Alliance").

Alliance delivers a provider's mobile system on a regular schedule that is also flexible enough to grow as NorthCrest's scan volume increases. Along with the equipment and transportation, Alliance provides qualified technologists, maintenance, marketing, and referring physician education. The logistics team also works closely with each new customer to assist with site development and electrical planning. Alliance can also perform a diagnostic evaluation to measure the overall level of customer satisfaction and determine when it may make sense to expand the level of service or consider building a fixed site.

3. Indicate applicant's legal interest in equipment (*i.e.*, purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

Response: The applicant intends to lease the equipment. Please see attached draft lease included as Attachment B-II-E(3).

- III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which <u>must</u> include:
  - Size of site (in acres);
  - 2. Location of structure on the site; and
  - 3. Location of the proposed construction.
  - 4. Names of streets, roads or highway that cross or border the site.

Please note that the drawings do not need to be drawn to scale. Plot plans are required for <u>all</u> projects.

Response: Please see <u>Attachment B-III-A</u>, for an attached copy of the plot plan identifying the NorthCrest campus. The location of the mobile pad is included on the plot plan. The hospital occupies a site of approximately thirty seven (37) acres, on U.S. Hwy. 431.

(B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

Response: Please see response to the CON review standards and criteria for PET included below.

b. Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c)

Response: Not applicable.

### **CON REVIEW STANDARDS AND CRITERIA**

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

**Response:** The table below identifies the type of procedures with an estimate of the number that will be performed in the first 3 years of operation. In addition to its uses for cancer detection, the scanner is used by neurologists, pulmonologists, general surgeons, and vascular surgeons.

### Estimated Utilization for PET by Patient Clinical Diagnoses Category (ICD-9)

	ICD-9 code	2015	2016	2017
Total # of Procedures		200	250	263
Stroke	434.91	16	20	21
Alzheimer	331	14	18	18
Parkinson's	332	14	18	18
Breast	174	40	50	53
Colon/Rectum	153	36	45	47
Lung/Bronchus	162	48	60	63
Prostate	185	32	40	42
Total		200	250	263

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

Response: NorthCrest anticipates initiating the PET service one half day per week with the flexibility to offer it a second half day as necessary, potentially increasing the service to a third half day per week. The applicant proposes 200 scans the first year of operation, gradually growing to 263 in the third year of operation. NorthCrest feels that these estimates are conservative and has based them in part on the number of scans it performed prior to its discontinuance of the service as well as discussions with the oncologists who practice in Robertson County. The oncologists are very supportive of the necessity to provide PET services in Robertson County. They feel it is necessary to have the flexibility to provide the service more than one half day per week in order that patients in Robertson County may receive the service as close to home as possible, in the least restrictive setting. The ability to receive the service in



5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

**Response:** NorthCrest Medical Center is the sole community provider in Robertson County. There are no unimplemented CONs in Robertson County. PET services are not currently provided in Robertson County.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology <u>must include</u> detailed calculations or documentation from referral sources, and identification of all assumptions.

Response: See utilization charts below.

**Hospital Utilization** 

Year	Occupancy (%)
2012	43%
2013	38%
2014	34%
2015	34%
2016	34%

**PET Projected Utilization** 

Year	Number of Procedures
2015	200
2016	250
2017	263

NorthCrest anticipates initiating the PET service one (1) half day per week, with the flexibility to offer a second half day. The applicant proposes 200 scans the first year of operation, gradually growing to 263 in the third year of operation. NorthCrest feels that these estimates are conservative and has based them in part on the number of scans it performed prior to its discontinuance of the service as well as discussions with the oncologists and other physicians who practice in Robertson County. The oncologists and the other physicians are very supportive of the necessity to provide PET services in Robertson County. They feel it is necessary to have the flexibility to provide the service on more than one half day per week in order that patients in Robertson County may receive the service as close to home as possible, in the least restrictive setting. The ability to receive the service in Robertson County means less disruption to both the patient's work schedule as well as any family members who are assisting in the receipt of medical services by the patient.



# PROJECT COSTS CHART

Α.	Cons	truction and equipment acquired by purchase:		
	1.	Architectural and Engineering Fees	-	-0-
	2.	Legal, Administrative (Excluding CON Filing F Consultant Fees	ee),	\$35,000
	3.	Acquisition of Site	-	-0
	4.	Preparation of Site		-0
	5.	Construction Costs	p -	-0
	6.	Contingency Fund	-	-0-
	7.	Fixed Equipment (Not included in Construction Contra	act)	-0
	8.	Moveable Equipment (List all equipment over \$50,00	)0)	-0-
	9.	Other (Specify)	:	-0-
B.	Acqu	isition by gift, donation, or lease:		
	1.	Facility (inclusive of building and land)	-	-0-
	2.	Building only		-0
	3.	Land only		-0-
	4.	Equipment (Specify) Mobile PET Unit	:	\$154,500
	5.	Other (Specify) Supplies - Radiopharmaceuti	cals	\$30,000
C.	Finar	ncing Costs and Fees:		
	1.	Interim Financing		-0-
	2.	Underwriting Costs	-	-0-
	3. ,,	Reserve for One Year's Debt Service	_	-0-
	4.	Other (Specify)	-	-0-
D.	Estim	nated Project Cost (A+B+C)	-	\$184,500
E.	CON	Filing Fee		3,000
F.	Total (D+E	Estimated Project Cost ) TO	TAL	<u>\$187,500</u>



# PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in July (Month).

III JI	uly (IV	ionin).		Ye	ar 2015	Yea	r 2016
A.	Utili	zation Data (Number of Proced	ures)		200		250
B.	Rev	venue from Services to Patients					
	1.	Inpatient Services		\$_		\$_	
	2.	Outpatient Services			\$735,800		\$919,750
	3.	Emergency Services		\$_		\$_	
	4.	Other Operating Revenue (Sp	pecify)	\$_		\$_	
		Gı	ross Operating Revenue		\$735,800		\$919,750
C.	Dec	luctions from Gross Operating F	Revenue				
	1.	Contractual Adjustments			\$485,628		\$607,035
	2.	Provision for Charity Care			\$22,074		\$27,593
	3.	Provisions for Bad Debt			\$29,432		\$36,790
			<b>Total Deductions</b>		\$537,134		\$671,418
NET	OP	ERATING REVENUE			\$198,666		\$248,333
D.	Оре	erating Expenses					
	1.	Salaries and Wages		\$_		\$_	
	2.	Physician's Salaries and Wag	es	\$_		\$_	
	3.	Supplies			\$30,000		\$38,625
	4.	Taxes		\$_		\$_	
	5.	Depreciation		\$_		\$_	
	6.	Rent			\$154,500		\$159,135
	7.	Interest, other than Capital		\$_		\$_	
	8.	Management Fees:		•		•	
		<ul><li>a. Fees to Affiliates</li><li>b. Fees to Non-Affiliates</li></ul>		\$ \$		\$ \$	•
	9.	Other Expenses – Specify on	separate page 12				
		To	otal Operating Expenses		\$184,500		\$197,760
E.	Oth	er Revenue (Expenses) Net (	(Specify)	\$_	- 15	\$_	
NET	OPE	ERATING INCOME (LOSS)			\$14,166		\$50,573
F.	Cap	ital Expenditures					
	1.	Retirement of Principal		\$_		\$_	
	2.	Interest		-		_	
	5),	То	tal Capital Expenditures	\$_		\$_	
		ERATING INCOME (LOSS) APITAL EXPENDITURES			\$ <u>14,166</u>		\$ <u>50,573</u>

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

**Response:** NorthCrest anticipates a net operating income of \$14,166 the first year of operation, increasing to \$55,573 the second year of operation.

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

**Response:** NorthCrest anticipates positive cash flow the first year of operation.

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

**Response:** NorthCrest anticipates 18% TennCare/Medicaid, 43% Medicare, 3% charity care and 4% bad debt based on gross revenues. The TennCare net operating revenue is projected to be \$35,760 in 2015 and the Medicare net operating revenue is anticipated to be \$85,426.

Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.

**Response:** Please see copy of balance sheet and income statement and the most current audited financial statements included as Attachment C, Economic Feasibility-10.

- Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:
  - a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

Response: There are no less costly, or effective or efficient ways to provide a diagnostic tool such as PET than through a mobile service. The costs of providing such a service on a mobile basis allow a provider who needs the service, but cannot justify or afford it on a full-time basis the ability to provide a necessary diagnostic tool to meet the health care needs of its patient population.

b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.



### **AFFIDAVIT**

STATE OF TENNESSEE
COUNTY OF DAVIDSON

NAME OF FACILITY: NorthCrest Medical Center - CN1504-013

I, Kim H. Looney, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 29th day of April, 2015, witness my hand at office in the County of Davidson, State of Tennessee.

NOTARY PUBLIC

My commission expires

HF-0043

Revised 7/02

STATE
OF
NOTARY
PUBLIC
OF DAMESTION EXPIRES:
JANUARY 8, 2019

# Copy SUPPLEMENTAL - #1

NorthCrest Medical center CN1504-013



Waller Lansden Dortch & Davis, LLPPLE 380 manu 511 Union Street, Suite 2700 P.O. Box 198966 Nashville, TN 37219-8966

Kim Harvey Looney 615.850.8722 direct kim.looney@wallerlaw.com

April 22, 2015

### VIA HAND DELIVERY

Jeff Grimm **HSDA** Examiner Tennessee Health Services and Development Agency 9<sup>th</sup> Floor 502 Deaderick Street Nashville, TN 37243

Re: NorthCrest Medical Center CN1504-013 - Certificate of Need for Initiation of PET Service

on Hospital Campus

Dear Jeff:

This letter is submitted as the supplemental response to your letter dated April 16, 2015, wherein additional information or clarification was requested regarding the above-referenced CON application.

### Section A, Applicant Profile, Item 9 1.

Please provide a bed complement table for the response and submit as replacement page 4 of the application.

Response:

See attached bed complement table included as Attachment A-9.

### 2. Section B, Applicant profile, Item 13

An immediate benefit of the project appears to be participation in the hospital's PET service by members of Southern Radiology Associates. With respect to payment for services, review of Item 1.3.6 of the former contract between the applicant and the hospital appears to confirm coordination of insurance benefits between the parties pertaining to participation by SRA in Medicare, Medicaid and other insurance plans in which the hospital participates. Review of Item 1.9 reflects that SRA must accept assignment of Medicare and Medicaid benefits on all Medicare and Medicaid patients. Given the expiration of the former agreement on 2/1/2015 and no replacement documentation for same such as a draft working agreement between the parties, please describe the arrangement planned for the proposed service. Will the hospital bill on a global basis, collect payments for services and reimburse the SRA radiologists on some prearranged basis? If billing separately, it would be helpful to include names, medical and provider license numbers of the SRA radiologists involved in this regard.

Response: It is anticipated that a contract that is substantially similar to the previous contract for SRA will be used should this PET service be approved, and it has been included for purposes of a draft agreement. The purpose of the contract is to ensure that the professional portion of the PET service is covered, including any supervision, if necessary. The previous contract includes an auto-renewal

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provision, so technically it is an ongoing agreement. The hospital will not bill globally, but only for the technical component. The radiologists will be responsible for billing and collecting for the professional services provided. A list of the radiologists for SRA is included below, along with the medical provider license numbers. Any of these radiologists might be responsible for the professional component for these proposed PET services. W. Wesley Brewer, M.D. will serve as the Medical Director.

List of Radiologists	<u>License</u>
Nathan R. Berkley, MD	39255
Brice T. Boughner, MD	44452
W. Wesley Brewer, MD	40361
James B. Butler, MD	21236
Gregory M Galdino, MD	42217
Daniel Grippo, MD	39219
James Grippo, MD	41992
Josh M. Heck, MD	49141
Robert J Mahoney, MD	35641
Joseph E. Pate, MD	26817
Gary T Podgorski, MD	15386
Michael S. Rissing, MD	51888
David M. Shackelford, MD	41711
Matthew Stephenson, MD	49955

### 3. Section B, Project Description, Item I

The executive summary is noted. Please provide brief remarks that identify the ownership structure, the need for the mobile service based on the extent of resident outmigration for PET services at other provider locations, and a brief description of the financial performance of the project in terms of sustainability of the service in light of the hospital's unfavorable net operating income reflected in the Historical Data Chart and audited financial statements (Statement of Operations) provided in the application.

Response: The PET service will be provided as an outpatient service of the hospital so there is no separate ownership structure for the service itself. The PET service is anticipated to generate positive revenue. As a rural non-profit acute care provider, NorthCrest has been working very hard to reverse a decline in the financial performance of the hospital. Since 2013, as is shown in its financial statements, NorthCrest has made positive strides in reducing the decline in operating income, partly by working to cut its expenses. The prior decline in operating income in 2013 was significantly decreased in 2014 and again year to date 2015. NorthCrest has also been evaluating the services it provides and seeking to strengthen its outpatient services. The ability to add PET services to the array of outpatient services offered will assist patients in receiving quality care close to home, as well as allow NorthCrest to continue to increase the outpatient services it provides, which will help alleviate the financial burden on a sole

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community, rural, non-profit hospital provider. The patients who reside in Robertson County and the surrounding areas want to receive their health care services in their communities; they do not want to come to an unfamiliar place like Nashville to receive medical services. To do so is confusing and more time consuming than receiving the services locally.

Because the service is not currently provided in Robertson County, providers ordering PET scans must refer patients to other counties for PET services. According to the HSDA Equipment Registry, the top 3 providers for PET scans by Robertson County residents are Imaging Alliance, Tennessee Oncology, and VUMC, all located in Davidson County. In 2013, according to the HSDA Equipment Registry, these 3 providers collectively performed 248 scans, or 93% of the total scans for Robertson County residents.

Please explain in more detail why the hospital and the equipment vendor did not know that PET was a reviewable Certificate of Need service immediately prior to or during the 17 months the mobile PET service was operated at NorthCrest Medical Center.

Response: There was some confusion as to whether or not a CON was required to initiate PET services, and which entity was the entity that needed to have the CON to provide PET services. NorthCrest did not realize it had to be the entity to receive a CON to provide PET services. When Alliance added NorthCrest to its radiopharmaceuticals license with the State of Tennessee, NorthCrest was under the impression that was the only approval that was necessary for it to begin providing PET services. NorthCrest thought it was covered under the mobile provider, but was under the impression that if it were to implement the service on a fixed basis, it would have to have its own CON. The error was discovered in the process of researching the requirements to have fixed PET services. At that time, NorthCrest immediately discontinued the service and made plans to file a CON to initiate the PET service. All of the PET scans that were performed received prior approval from the payers, including Medicare and TennCare.

### 4. Section B, Project Description, Item II.C

The applicant states that the oncology services provided to residents of Robertson County have increased in recent years. However, review of the hospital's 2013 Joint Annual Report (JAR) revealed that the hospital did not provide chemotherapy services or radiation therapy services during the period. Additionally, surgery volumes related to cancer cannot be determined from the JAR. As such, additional description of the hospital's cancer program is needed. Please address the following items:

A) The incidence of cancer in Robertson County compared to statewide rates using information available through the Tennessee Department of Health,

Response: According to the report, Cancer in Tennessee 2006-2010, published in 2013 by the Tennessee Department of Health, the incidence of cancer in Robertson County was 494.9 per 100,000, which is 3.1% higher than the overall Tennessee rate of 479.9 per 100,000.

B) The nature and scope of the hospital's existing cancer programs through its participation in the Vanderbilt Health Affiliate Network (VHAN),

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Response: Many of the oncology services in an area are offered through physician providers and not hospital providers. Participation in VHAN has brought three (3) additional medical oncologists to Robertson County to provide services, and the Vanderbilt Ingram Cancer Center provides chemotherapy on NorthCrest's campus, thereby increasing access to oncology services for the service area residents. Tennessee Oncology also provides chemotherapy services to its patients in its space on the NorthCrest campus. PET is currently the only diagnostic service for cancer that is currently not provided on NorthCrest's medical campus.

C) A description of the hospital/medical staff organizational structure for coordinating the activities of the oncology program,

**Response:** All medical staff involved in the cancer program participate in the tumor board to discuss incidence, types, treatments and outcomes of cancers. In general, the medical oncology services provided by the particular oncology providers are directed by their practices and not the hospital. Each practice is responsible for the medical care of their patients.

D) A description of the hospital's tumor registry and tumor board and information systems support for these activities, and

Response: NorthCrest Medical Center utilizes a contracted tumor registrar to complete all reporting to the Tennessee Cancer Registry.

Tumor Board – Dr. Anjali Sibley directs the tumor board at NorthCrest Medical Center which assembles monthly for tumor conference. All health information systems utilized at NorthCrest are utilized collaboratively as applicable to support both Tennessee Cancer Registry reporting and tumor board activities.

E) A description of how the proposed PET service can contribute to any clinical investigative protocols through formal oncology network relationships with other providers.

**Response:** This proposal will allow NorthCrest, through its formal relationships with the Vanderbilt Ingram Cancer Center, and Tennessee Oncology to participate in clinical trials. PET is currently the one diagnostic tool that is missing for oncology services at NorthCrest.

Positron emission tomography (PET) has become an essential tool in detecting cancer throughout the body. A PET scan is very different from an ultrasound, X-ray, MRI, or CT. Unlike these imaging technologies which merely confirm the presence of a mass, a PET scan can distinguish between benign and malignant disorders. A PET scan can detect abnormalities in cellular activity, generally before there is any anatomical change. PET is able to diagnose disease before structural changes become detectable with anatomical imaging techniques, potentially improving the prognosis. PET scans allow doctors to detect abnormalities in glucose metabolism, which is a hallmark of cancer cells. PET scans assist in the diagnosis and staging of cancer. PET helps avoid the expense and pain of removing benign nodules, as well as invasive biopsy procedures to determine malignancy. Reports in the scientific literature find that,

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in some tumors, PET correctly identifies detected lesions 95% of the time. Because PET can survey the whole body, PET can identify distant, occult metastases that may affect the course of treatment and therefore change patient management. PET scans can also be used to determine if treatment has destroyed all of a patient's cancer.

The applicant states that the previous service averaged approximately 8 PET procedures per month from September 2013 through February 2015. At that rate, it appears that approximately 136 PET procedures were performed during the 17 month period in lieu of the 227 procedures (average of 13 per month) indicated in your response on page 9 of the application. Please clarify.

**Response:** The applicant incorrectly identified the average PET procedures per month. The average of 13 PET procedures per month is correct as are the total procedures of 227 for the 17 month time period.

Review of HSDA Equipment Registry records revealed that residents of Robertson County had approximately 266 PET procedures at Tennessee provider locations in calendar year (CY) 2013, excluding PET utilization of Robertson County residents at Northcrest during the 12-month period. Assuming residents of the county had approximately 100 scans at Northcrest in CY2013 (8 per month x 12 months), it would appear that the residents had approximately 366 PET procedures in 2013. With this in mind, the applicant's projections for 475 PET procedures in Year 1 (2015) increasing by 21% to 573 procedures in Year 2 appear to exceed resident demand for the service. Please explain how utilization by residents of the county can support the projected volumes identified for the proposed 2-3 day per week mobile service.

Response: When the correct average number of scans performed is utilized, there were 156 scans (rather than 100) performed at NorthCrest, for a total of 422 PET procedures in 2013, when this number is applied to the numerical assumptions used above. As stated in the application, if NorthCrest offers the service on more than one day during the week, the physicians who order the scans are anticipated to order more locally, as that is the best option for the provision of this important diagnostic tool. Not all patients are Robertson County residents.

The applicant states in the application that the majority of the patients are expected to come from Robertson County residents. That does not mean that only patients from Robertson County will utilize the service. Perhaps a better way to describe the service area is to identify Robertson County as the primary service area, with a secondary service area of Cheatham and Montgomery Counties. In addition, as NorthCrest is on the Kentucky border, patients from Kentucky also utilize the medical services it offers

NorthCrest reviewed the utilization of the PET services and determined that while 76% of the services provided were for Robertson County residents, 24% of the utilization was in secondary markets outside of Robertson County. The referring physicians have requested an additional day for the PET service.



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NorthCrest based its projection of 475 scans in year one from the following geographic areas:

%/Number	State / County
5/24	Kentucky
5/24	Cheatham
10/48	Montgomery
2/9	Sumner
2/9	Davidson
76/361	Robertson

Cheatham and Montgomery Counties are the two Tennessee counties comprising the majority of the secondary service area. According to the HSDA equipment registry data for 2013, 241 Montgomery County patients and 156 Cheatham County patients utilized PET scan services outside of their respective counties. These patients who received PET services outside of their resident counties traveled to virtually the same PET service locations as the Robertson County residents. Since the NorthCrest location would be a more convenient location for many of these patients, as outlined above, some of them would likely be captured by the new PET service at NorthCrest should the requested CON be approved. Below is the population data for the two counties comprising the majority of the secondary service area, Cheatham and Montgomery:

### Secondary Service Area

Cheatham County				
Age	2015	2019	% Change	
0 to 19	9,975	8,517	(14.6)	
20 to 44	10,916	10,103	(7.4)	
45 to 64	14,082	16,269	15.5	
65 to 74	3,743	4,713	25.9	
75 plus	1,372	1,363	(.66)	
Total 65 plus	5,115	6,076	18.8	
Total	40,088	40,965	2.2	

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Montgomery County				
Age	2015	2019	% Change	
0 to 19	61,953	67,744	9.3	
20 to 44	71,655	71,626	(.04)	
45 to 64	40,491	44,331	9.5	
65 to 74	10,414	12,310	18.2	
75 plus	6,555	7,449	13.6	
Total 65 plus	16,969	19,759	16.4	
Total	191,068	203,460	6.5	

Total Secondary Service Area				
Age	2015	2019	% Change	
0 to 19	71,928	76,261	6.0	
20 to 44	82,571	81,729	(1.0)	
45 to 64	54,573	60,600	11.0	
65 to 74	14,157	17,023	20.2	
75 plus	7,927	8,812	11.2	
Total 65 plus	22,084	25,835	17.0	
Total	231,156	244,425	5.7	

As is shown in the population charts above, and in the charts in the application, the population aged 65 and older is expected to increase significantly between 2015 and 2019, for both the primary and secondary service areas, well over the increase for the total population in these counties. It is the 65+ age group which is expected to be the highest users of PET services.

### 5. Section B, Project Description, Item II.E.

<u>Item 2.a</u> – Please provide the name of the unit, year manufactured, and date acquired by the vendor. Excluding downtime for maintenance, how long has the mobile unit been in use?

**Response:** The mobile unit is a PET/CT 119, manufactured in 2006, and was acquired December 1, 2008, by the mobile vendor, and has been in continuous use since that time.

Please identify all existing sites of the proposed mobile unit, distance from the applicant and days of week they are scheduled.

Response: It is the applicant's understanding that the mobile vendor provided services to the following providers with the same PET/CT scanner, during the time NorthCrest first initiated the service. These routes may be adjusted and/or an additional scanner used to provide services to NorthCrest for its proposed Thursday/Friday and potentially Monday operation. NorthCrest proposes to offer the services on a convenient schedule for patients. The more different days on which it can offer the services, the

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more of the outmigration it should be able to capture. Since none of the proposed days are full days, the applicant is proposing services for up to a total of 1 ½ days per week. The applicant proposed Tuesday and Thursday mornings for initial times of operation, but has since revised the proposed schedule to Thursday afternoon, Friday morning, and potentially Monday morning, should it be needed, after further discussions with the mobile vendor.

Williamson Medical Center: Franklin, TN – Monday – 50 miles

Maury Regional: Columbia, TN – Monday – 50 miles

BMH- Desoto; Southhaven, MS – every other week – Wed, Thurs – 250 miles

BMH- Union City: Union City, TN – Friday – 170 miles

Harton Regional: Tullahoma, TN – First Sat. of every month, and the following 2 weeks on Wed – 100 miles.

<u>Item 2.b</u> – the applicant states that the service may be provided up to 3 days per week to meet the needs of service area residents. Please explain why this is necessary when the prior service operated 1 day per week over the 17 months ending February 2015.

**Response:** NorthCrest anticipates providing the service initially 2 half days per week to service the needs of the residents of Robertson County and surrounding areas to provide convenient access to those patients who find unnecessary travel a hardship and prefer to obtain a PET scan locally, and with minimal travel time. If utilization warrants an increase in the amount of time the service is offered, NorthCrest would like to be able to offer up to 3 half days per week to meet those needs. As stated previously there is no PET service provider within approximately 30 miles of NorthCrest Medical Center.

The referring physicians in the area feel it is necessary to provide the PET service more than one day per week in order that patients in Robertson County may receive the service as close to home as possible, in the least restrictive setting. The ability to receive the service in Robertson County means less disruption to both the patient's work schedule as well as any family members who are assisting in the receipt of medical services by the patient.

The CON application proposed that the PET services be provided on Tuesday and Thursday mornings. After further discussions with the equipment vendor, NorthCrest has adjusted the schedule of operations and anticipates providing the services initially on Thursday afternoon and Friday morning for half a day each, and when justified, expanding the service additional half day a week to Monday. That way, the mobile scanner does not have to be moved during the week to go and come back to NorthCrest, but is on a less disruptive schedule.

<u>Item 2.c</u> – The applicant states that the cost of the lease has not yet been determined. At a minimum, documentation of the equipment lease should be provided in the form of a Letter of Intent between the hospital and the equipment vendor in lieu of the expired lease agreement used for the previous arrangement. Please clarify by providing the documentation requested to support the Project Cost of the application.

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**Response:** Please see <u>Attachment 5.B-Item II.E.(2c)</u> lease for the equipment. The equipment vendor has structured it as an amendment to the original lease, which has an evergreen clause. The applicant anticipates that the amount of the lease will be the same as during the time it was previously performing the service and has included that amount - or \$3,090 per day of service - in it projected costs.

Who does the equipment vendor use to obtain the FDG/radioactive material at the cost of \$150 per dose? Please provide the name of the supplier and address. Please also identify the distance to the closest cyclotron source. Are these costs reflected in the Project Cost Chart on page 20?

**Response:** NorthCrest anticipates that the mobile provider will receive the radiopharmaceuticals from the Vanderbilt entity identified below, which is approximately 30 miles away. The costs for the dose are included in the Projected Cost Chart in Other Supplies. A revised Project Cost Chart has been included as Attachment 5-Item II.E2(c) to identify these other supplies as the radiopharmaceuticals.

PETNET – Vanderbilt MRB, Room 1251 2222 Pierce Avenue Nashville, TN 37232-6315

<u>Item 2.d</u> - Please provide documentation from the equipment vendor that describes how the \$225,000 fair market value estimate of the mobile unit was determined.

Response: Please see <u>Attachment 5.B-Item II.E.(2d)</u> letter identifying the FMV of the mobile unit at \$225,000.

### 6. Section C. Need Item 1. (Project Specific Criteria – PET Service)

Item 1—Patients with cancer diagnoses appear to account for approximately 78% of the 475 projected PET procedures shown in the table on page 12 for Year 1. Please include the cancer incidence rate of Robertson County residents for the most recent period available in documentation in information maintained by the Department of Health or other sources of population data.

Response: According to the report, Cancer in Tennessee 2006-2010 published in 2013 by the Tennessee Department of Health, the incidence of cancer in Robertson County was 494.9 per 100,000, which is 3.0% higher than the overall Tennessee rate of 479.9 per 100,000.

As noted, please justify the increase in PET procedures at the amounts indicated in light of both the applicant's prior utilization and resident PET procedures. For resident PET procedures, please show for 2011 – 2013 by contacting Alecia Craighead, Stat III, HSDA.

Response: The applicant states in the application that the majority of the patients are expected to come from Robertson County residents. That does not mean that only patients from Robertson County will utilize the service. Perhaps a better way to describe the service area is to identify Robertson County as

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the primary service area, with a secondary service area of Cheatham and Montgomery Counties. In addition, as NorthCrest is on the Kentucky border, patients from Kentucky also utilize the medical services it offers.

NorthCrest reviewed the utilization of the PET services and determined that while 76% of the services provided were for Robertson County residents, 24% of the utilization was in secondary markets outside of Robertson County. The referring physicians have requested an additional day for the PET service.

NorthCrest based its projection of 475 scans in year one from the following geographic areas:

%/Number	State / County
5/24	Kentucky
5/24	Cheatham
10/48	Montgomery
2/9	Sumner
2/9	Davidson
76/361	Robertson

Cheatham and Montgomery Counties are the two Tennessee counties comprising the majority of the secondary service area. According to the HSDA equipment registry data for 2013, 241 Montgomery County patients and 156 Cheatham County patients utilized PET scan services outside of their respective counties. These patients who received PET services outside of their resident counties traveled to virtually the same PET service locations as the Robertson County residents. Since the NorthCrest location would be a more convenient location for many of these patients, as outlined above, some of them would likely be captured by the new PET service at NorthCrest should the requested CON be approved.

Below is a chart with data from the HSDA showing the Robertson County resident PET procedures for 2011-2013:

	2011	2012	2013
Robertson County Resident Procedures at all TN Provider Sites	314	279	266
Total Resident PET Procedure Rate per 1,000 population	4.68	4.09	3.84
Statewide PET Rate per 1,000 population	4.64	4.60	4.30

HSDA Equipment Registry, TDH population estimates

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Item 4- The referral arrangements with Vanderbilt Ingram Cancer Center and Tennessee Oncology are noted. Given the absence of chemotherapy services and radiation therapy services at Northcrest, what arrangements are planned for referrals to other facilities in contiguous counties such as Davidson County? As part of same, what assurances will be provided for acceptance of PET scans performed by the applicant? Under what circumstances will rescanning be necessary?

Response: NorthCrest offers medical and surgical oncology services on-site through its relationship with Vanderbilt Ingram Cancer Center and Tennessee Oncology. Additionally its medical staff have existing referral relationships with regional medical centers for oncology care. Both the Vanderbilt Ingram Cancer Center and Tennessee Oncology, offer chemotherapy services on the NorthCrest Medical Center campus. The closest radiation therapy services are provided by these providers in either Clarksville or Nashville. NorthCrest does not anticipate that rescanning for PET services will be necessary as the scans will be ordered by the providers who will be using them. Of course, during the course of treatment, additional scans may be ordered to track the effectiveness of treatment.

Item 6.c. – Please also address the hospital's procedures to be implemented in the event of a spill of the radioactive material used for the mobile PET unit. What are the responsibilities of the medical director or appropriate hospital personnel for same?

**Response:** Please see <u>Attachment C-Need-Item6(c)</u> Hospital policy. NorthCrest will provide physician supervision for the PET/CT service, with radiologist interpretation onsite provided by SRA. Alliance will provide a PET Certified Nuclear Medicine Technologist as part of the provision of the PET scanner.

Item 6.f.-it appears that the response would include comment about SRA physicians being active members of the hospital medical staff. Please clarify.

**Response:** The Medical Director, as well as all SRA physicians, are credentialed as active members of NorthCrest Medical Center's medical staff.

Item 8.b – please include comment here about findings of the cancer incident rate for residents of Robertson County. Please also compare to the statewide average rate for the most recent 12 month period available.

**Response:** According to the report, Cancer in Tennessee 2006-2010 published in 2013 by the Tennessee Department of Health, the incidence of cancer in Robertson County was 494.9 per 100,000, which is 3% higher than the overall Tennessee rate of 479.9 per 100,000. In addition, the mortality rate in Robertson County is 210.5, which is 6% higher than the overall Tennessee rate of 198.2.

### 7. Section C, Need, Item 3 (Service Area)

Please complete the table below documenting resident PET utilization:

4820-7326-6467.6

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	2011	2012	2013
Robertson County Resident Procedures at all TN Provider Sites	314	279	266
Total Resident PET Procedure Rate per 1,000 population	4.68	4.09	3.84
Statewide PET Rate per 1,000 population	4.64	4.60	4.30

HSDA Equipment Registry, TDH population estimates

As noted elsewhere, the data reported to the HSDA Equipment Registry does not include utilization for PET procedures performed at NorthCrest.

### 8. Section C, Need, Item 5

The absence of other PET providers in Robertson County is noted. Please identify the use of PET providers in Davidson County and other areas of TN by residents of Robertson County for the most recent 3 years. A suggested template is provided in the table below. Please contact Alecia Craighead, HSDA Stat III for assistance with data from the HSDA Equipment Registry.

PET Utilization by Robertson County Residents, 2011-2013

Providers with PET Service	Provider Location	Distance from Applicant (Miles)	2011	2012	2013	% Change '11-'13
Premier	Davidson	32.1	0	0	10	0.0%
Imaging Alliance	Davidson	31.4	86	118	94	9.3%
TN Oncology	Davidson	32.0	130	88	89	(31.5%)
Centennial	Davidson	33.8	10	10	5	(50.0%)
VUMC	Davidson	32.9	42	58	65	54.76%
St. Thomas Midtown	Davidson	27.5	36	0	0	(100.0%)
Subtotal-Davidson County			304	274	263	(13.5%)
Gateway Medical Center	Montgomery	32.9	6	4	3	(50.0%)
Tennessee PET Scan Center	Rutherford	55.1	2	0	0	(100.0%)
East Memphis PET Imaging Center, LLC	Shelby	227	2	1	0	(100.0%)
All other TN providers			10	5	3	(70.0%)
Total -TN			314	279	266	(15.3%)

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•Note: new provider Source: HSDA Equipment Registry, 2013 Service Utilization Records

### 9. Section C, Need. Item 6 (applicant's projected Utilization)

It appears that the applicant is projecting utilization in Year 1 that amounts to approximately 130% of the total estimated utilization of Robertson County residents in 2013. Please explain how this is possible by explaining the methodology that was used to project PET volumes of the project in more detail.

Response: As stated previously, because the average number of scans performed per month at NorthCrest was 13, rather than the 8 reported in the original application, utilization is not 130%. When the correct average number of scans performed is utilized, there were 156 scans (rather than 100) performed at NorthCrest, for a total of 422 PET procedures in 2013, when this number is applied to the numerical assumptions used above. As stated in the application, if NorthCrest offers the service on more than one day during the week, the physicians who order the scans are anticipated to order more locally, as that is the best option for the provision of this important diagnostic tool. Not all patients for PET services are Robertson County residents.

The applicant states in the application that the majority of the patients are expected to come from Robertson County residents. That does not mean that only patients from Robertson County will utilize the service. Perhaps a better way to describe the service area is to identify Robertson County as the primary service area, with a secondary service area of Cheatham and Montgomery Counties. In addition, as NorthCrest is on the Kentucky border, patients from Kentucky also utilize the medical services it offers.

NorthCrest reviewed the utilization of the PET services and determined that while 76% of the services provided were for Robertson County residents, 24% of the utilization was in secondary markets outside of Robertson County. The referring physicians have requested an additional day for the PET service.

NorthCrest based its projection of 475 scans in year one from the following geographic areas:

%/Number	State / County
5/24	Kentucky
5/24	Cheatham
10/48	Montgomery
2/9	Sumner
2/9	Davidson
76/361	Robertson

Cheatham and Montgomery Counties are the two Tennessee counties comprising the majority of the secondary service area. According to the HSDA equipment registry data for 2013, 241 Montgomery

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County patients and 156 Cheatham County patients utilized PET scan services outside of their respective counties. These patients who received PET services outside of there resident counties traveled to virtually the same PET service locations as the Robertson County residents. Since the NorthCrest location would be a more convenient location for many of these patients, as it is located between I-65 and I-24, some of them would likely be captured by the new PET service at NorthCrest should the requested CON be approved.

In your response, please summarize the strategies that NorthCrest would need to implement to capture all outmigration of residents to providers outside the county. What are the key factors that will determine whether or not the capture rate methodology is attainable?

Response: Accessibility and ease of use is the key to capturing the majority of Robertson County. A large portion of the existing outmigration is primarily due to the existing physicians, primarily those from Vanderbilt and Tennessee Oncology ordering scans in Nashville. These two groups alone accounted for 154 scans for Robertson County residents. If some of this outmigration is halted, NorthCrest can easily justify the number of PET scans it has proposed. These doctors have indicated that the convenience and ease of the ability to access the PET services locally greatly enhance the patient care they can provide and if the service were offered more than one day per week, they would utilize it more, because any delay in treatment would be minimized.

Please show the percentages by payor for the propose service in Year 1 of the project by completing the table below.

Payor Source	Year 1 Gross Revenue (as a % of total)	Average Gross Charge per PET procedure	Year 1 Gross Revenue (as a % of total)
Medicare	43	3,679	751,436
TennCare	12	3,679	209,703
Managed care	14	3,679	244,654
Commercial	23	3,679	404,520
Self-Pay	1	3,679	16,181
Other	7	3,679	121,032
Total	100	3,679	1,747,525

Mobile PET Service Payor Mix, Year 1

### 10. Section C, Economic Feasibility Item 1 (Project Costs Chart)

The following definition regarding major medical equipment cost in Tennessee Health Services and Development Agency Rule 0720-9-.01 (13)(b) states "The cost of major medical equipment includes all costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: (1) maintenance agreements, covering the expected useful life of

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the equipment; (2) federal, state, and local taxes and other government assessments and (3) installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding."

Is the \$321,360.00 mobile PET unit equipment cost listed in Line A.7 of the Project Cost Chart consistent with the Rule? In your response, please provide a breakout of the key cost items of the fixed unit that apply to the project per Agency Rule above. If not, please make the necessary equipment cost adjustments and submit a revised Project Cost Chart.

**Response:** The unit is not a fixed unit but a leased mobile unit. The only costs associated are the day rental of the unit and the cost of radiopharmaceuticals. Any costs for maintenance are the responsibility of the mobile vendor. There are no renovations or capital expenses needed as unit is mobile and not fixed. Any costs listed are consistent with the appropriate rule.

### 11. Section C, Economic Feasibility, Item 4. (Projected Data Chart)

Line D.9 "Other Expenses" appears to be missing the anticipated mobile equipment lease cost with related costs for FDG, and expenses for contract fees with Southern Radiology Associates and/or related professional fees of the radiologists. Please identify same and provide a revised chart in a replacement page for the application labeled 26-R.

**Response:** The mobile rental rate is included under the Operating expense section under the Rental expense detail line, with an amount of \$321,360 (\$3,090 x 2 days x 52 weeks).

There are no additional fees paid to SRA; SRA bills and collects for the professional services it provides. The only fees payable to Alliance are the daily rate, plus the cost of the per patient PDG injection. A revised Projected Data Chart is not necessary.

Review of the Consolidated Statement of Operations in the attachments revealed differences in the entries for net operating revenue and net operating income from the amounts shown in the Historical Data Chart on page 25. As a result, it appears that the unfavorable net income may be higher than shown in the chart. Please clarify.

**Response:** The historical data chart provides information for the hospital only and not the consolidated information for all related entities. Both data sets are correct; they are just not the same.

### 12. Section C., Economic Feasibility, Item 6 B.

Please include a comparison to HSDA Equipment Registry PET charges in the response.

**Response:** According to the HSDA PET equipment registry for 2013, the average charge for a mobile PET procedure is \$5,684 per procedure. NorthCrest's proposed charges are on the low side of these charges.

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What are the arrangements for professional fees related to imaging interpretation services by radiologists? Are these reflected in the Projected Data Chart for the mobile service?

Response: SRA bills the professional component to each payer directly, and NorthCrest bills the technical component. There are no additional fees paid to SRA for this service and therefore no associated costs in the Projected Data Chart.

### 13. Section C, Economic Feasibility, Item 11 b.

A key benefit of the proposed service appears to be a more convenient and accessible site for residents of the county. Looking at distance/travel times as a key factor, what are the savings in mileage/driving times to the applicant's campus that residents of the service area could expect?

**Response**: Assuming an average of 30 miles to the next nearest PET or 60 miles round trip at \$.575 per mile, then the average Robertson County patient is saving \$34.50 per trip. In the consideration of time and aggravation, the average trip to Nashville (factoring traffic and construction delays) is twice to three times as long as the drive to NorthCrest. This is regardless of the location of the patient, from either the primary service area or the secondary service areas. Considering the average age of the patient, which is 65+, the drive is an important factor for ease of use.

What other key benefits should residents and their attending physicians be aware of in selecting NorthCrest's proposed PET service in lieu of other sites outside the service area?

Response: There are no existing providers of PET services in Robertson County. PET services are an essential tool in detecting cancer throughout the body. Unlike other imaging technologies which merely confirm the presence of a mass, a PET scan can distinguish between benign and malignant disorders. PET helps avoid the expense and pain of removing benign nodules, as well as invasive biopsy procedures to determine malignancy. The initiation of this service in Robertson County will allow more timely access to a necessary diagnostic tool and increase outcomes for its service area residents. In addition to its uses for cancer detection, the scanner is used by neurologists, pulmonologists, general surgeons, and vascular surgeons.

If this project is approved it will decrease drive times, provide more convenient access, and offer expert local interpretation for speed of diagnosis. If approved this project will significantly increase accessibility for local patients needing to obtain PET/CT examinations close to home.

The oncologists and other physicians providing services in Robertson County have indicated that they would prefer to send their patients to a location in Robertson County to receive PET services and the initiation of this service two days a week will allow them to do so for most patients, without unduly delaying diagnosis and treatment of those patients.

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### 14. Section C, Orderly Development, Item 4

It is understood technical staff will be provided by the equipment vendor. However, please show by position classification.

**Response:** The professional staff provided by the mobile vendor will include either a certified nuclear medical technologist (CNMT) an American Registry of Radiologic Technologists - Nuclear Medicine. (ARRT RT (N)).

### 15. Published Letter of Intent (LOI)

The LOI did not identify or otherwise specify the anticipated schedule such as number of days per week that the mobile PET service would be available at Northcrest. Please clarify why this information was omitted.

Response: NorthCrest Medical Center apologizes for inadvertently omitting this information from the LOI.

NorthCrest respectfully requests two half days of service, with the ability to increase to three half days when utilization so warrants. The current plan would be to initially provide two half days of consecutive service beginning Thursday afternoon from 1-5 p.m. and Friday 7:30-11:30 a.m., increasing to add Monday 7:30-11:30 a.m., as necessary. (The applicant initially proposed Tuesday and Thursday mornings, but upon further discussions with the mobile vendor, it has determined that this revised schedule will be better.) The unit will remain in service as long as required to serve patients needing service those particular days.

If you have any questions, please feel free to give me a call.

Sincerely,

Kim Harvey Looney

Loone

KHL:lag Encl.

# **SUPPLEMENTAL-1**

Attachment 1.A- -9
Bed Complement Table

9.	Bed Complement Data	-1: - 4:L4: -		,,41 <b>6</b> 141 -		iv bodo
	Please indicate current and proposed	Current Licensed		Staffed Beds	Beds Proposed	TOTAL Beds at Completion
	A. Medical B. Surgical	90	N/A	<u>51</u>	N/A	90
	C. Long-Term Care Hospital D. Obstetrical E. ICU/CCU		 N/A	9	N/A	 
	F. Neonatal G. Pediatric	<u>6</u> <u>8</u>	N/A	4 5	<u>N/A</u>	<u>6</u> <u>8</u>
	<ul><li>H. Adult Psychiatric</li><li>I. Geriatric Psychiatric</li></ul>	<u>5</u>	N/A	<u>0</u>	N/A	<u>5</u>
	<ul><li>J. Child/Adolescent Psychiatric</li><li>K. Rehabilitation</li><li>L. Nursing Facility (non-Medicaid Certified)</li></ul>					
	M. Nursing Facility Level 1 (Medicaid only) N. Nursing Facility Level 2 (Medicare only) O. Nursing Facility Level 2					
	(dually certified Medicaid/Medicare) P. ICF/MR Q. Adult Chemical Dependency					
	R. Child and Adolescent Chemical Dependency					
	S. Swing Beds T. Mental Health Residential Treatment					
	<ul><li>U. Residential Hospice</li><li>TOTAL</li><li>*CON-Beds approved but not yet in servi</li></ul>	109 ce	N/A	<u>75</u>	<u>N/A</u>	109
10.	Medicare Provider Number  Certification Type  440  Hos	065 pital				
11,	Medicaid Provider Number Certification Type  040 Hos	065 pital				
12.	If this is a new facility, will certification Response: N/A	ı be sough	nt for Med	dicare ar	id/or Medi	caid?
13.	Identify all TennCare Managed Care O (MCOs/BHOs) operating in the propositreatment of TennCare participants? yidentify all MCOs/BHOs with which the Response: The applicant has contracts United Healthcare Community Plan and Tennicus any out-of-network relationshipses N/A	ed services es If the e applican with all Te ennCare Se	e area. We respons t has cor nnCare Mect.	/ill this p e to this ntracted ICOs: A	roject invo item is ye or plans to merigroup,	olve the s, please o contract. BlueCare,

Attachment 5.B-, Item II.E.(2c) Lease

# ADDENDUM "A" TO THE PETCT MASTER SERVICES AGREEMENT

This Addendum modifies the PET/CT Master Services Agreement (the "Agreement"), fully executed on August 6, 2013, between Alliance HealthCare Services, Inc., a Delaware corporation, d/b/a Alliance HealthCare Radiology, located at 100 Bayview Circle, Suite 400, Newport Beach, California 92660 ("Alliance") and NorthCrest Medical Center, located at 100 Northcrest Drive, Springfield, Tennessee 37172 (the "Client").

The provisions of this Addendum shall become effective as of the date fully executed below. When properly executed below this Addendum shall be added to the above named Agreement.

INCORPORATION. This Addendum shall consist of the following documents 1) Addendum "A" and 2) Memorandum of Understanding.

Section 3 of the Agreement Cover Page, is hereby replaced in its entirety to read as follows:

#### 3. Fees.

The fees exclude radiopharmaceuticals.

Notwithstanding anything to the contrary in this Agreement, all PET and PET/CT procedures performed under this Agreement shall be restricted to the use of only FDG (fluorine-18-deoxy-glucose) and such other PET radiopharmaceuticals that Alliance and Client agree in writing to use that are approved for clinical use by the Nuclear Regulatory Commission (NRC) or applicable State under agreement with the NRC.

#### FLAT DAILY FEE.

Five (5) hour half day of service	\$
Radiopharmaceutical Charge per dose	\$
Hourly overtime beyond five (5) hours that an Alliance technologist is present at the Unit Location:	\$

a) PET/CT Procedure Schedule and Radiopharmaceuticals. Client shall, no later than 11:00 p.m. each business day, provide to the designated Alliance representative a written schedule of its Radiopharmaceutical requirements for the next business day, showing times and quantities. Client may cancel without financial obligation any prescheduled doses by notifying Alliance's supplier of radiopharmaceuticals at least one (1) business day prior to shipment and such shipment does not occur. In the event that a scheduled procedure cannot be completed due to the actions of Alliance, the costs for the prescheduled radiopharmaceutical shall be borne by Alliance. In the event that the scheduled procedure cannot be completed due to the actions of the Client employees, the cost of the prescheduled procedure cannot be completed due to the "no show" or patient cancellation at the time of the procedure, the cost of the radiopharmaceutical shall be borne by the Client at a rate of \$150 per dose. Above stated fees are for FDG doses up to 15mCi. If the base dose 15mCi price to Alliance increases by ten percent (10%) or more, the cost in excess of ten percent (10%) shall be charged to Client on a dollar-for-dollar basis. Client agrees to return all shipment cartons and containers to the designated Radiopharmaceutical Supplier in the same condition and shall be responsible for material damages, normal "wear and tear" excepted.

Section 4 of the Agreement Cover Page, is hereby replaced in its entirety to read as follows:

4 Scheduling. Alliance shall make the Unit available to the Client and any services that Alliance is obligated to provide under this Agreement, and Client agrees to accept the Unit and any such services, three (3) half days per week, five (5) hours per day. Alliance shall determine the specific service schedule.

Section 5(a) is hereby added to the Agreement Cover Page as follows:

5(a) Term Extension. The term of this Agreement is extended for an additional thirty-six (36) months following the current expiration date of September 25, 2015. The new expiration date is September 25, 2018. This Agreement shall not automatically renew.

Except as herein above provided, no other change, amendment or modification of the Agreement is hereby intended or implied, including but not limited to any prior drafts of this Addendum that have not been fully executed. Capitalized terms used in this Addendum shall have the same meanings as are set forth in the Agreement, except as otherwise indicated in this Addendum.

Alliance and Client acknowledge that they and their respective legal counsel have had the opportunity to participate equally in the drafting of this Addendum and that in the event of a dispute, no party shall be treated, for any purpose, as the author of this Addendum nor have any ambiguity resolved against it on account thereof.

By their signatures to this Addendum, each of the signatories to this Addendum represent that they have the authority to execute this Addendum and to bind the party on whose behalf their execution is made. This Addendum constitutes the legal, valid and binding obligation of the parties enforceable in accordance with its terms.

This Addendum may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Delivery of an executed counterpart of this Addendum may be made by facsimile or other electronic transmission. Any such counterpart or signature pages sent by facsimile or other electronic transmission shall be deemed to be written and signed originals for all purposes, and copies of this Addendum containing one or more signature pages that have been delivered by facsimile or other electronic transmission shall constitute enforceable original documents. As used in this Addendum, the term "electronic transmission" means and refers to any form of communication not directly involving the physical transmission of paper that creates a record that may be retained, retrieved and reviewed by a recipient of the communication, and that may be directly reproduced in paper form by such a recipient through an automated process.

Alliance and Client have duly executed this Addendum as of the last date written below.

ALLIANCE HEALTHCARE SERVICES, INC. d/b/a ALLIANCE HEALTHCARE RADIOLOG		MEDICAL CENTER	
Authorized Signature Richard W. Johns EVP, General Counsel and Corporate Secretary Date:	Authorized Signate Printed Name: Title: Date	ire	
FOR CONTRACTS USE ONLY: Contract #: 007612 DO: Darrin McCall	Customer #: 24244 Requestor: Michael Dougherty	Client Type: Hospital	

#### A fully executed document must be received prior to service commencement.

To Mail a Signed Document: Alliance HealthCare Services, Inc., ATTN: Contracts Administration Department, 100 Bayview Circle, Suite 400, Newport Beach, California 92660.

To Email a Signed Document: Contracts@allianceimaging.com

To Fax a Signed Document: 602-345-7637



#### Alliance HealthCare Services Inc. Memorandum of Understanding

Date:

- 1. An Alliance Authorized User will review the ordering physician's request of a PET/CT scan. An Alliance Authorized User will supervise PET/CT technical staff.
- 2. The Alliance Authorized User or RSO will ensure the PET/CT staff complies with safe use, storage and disposal of all radioactive materials according to the RAM license.
- 3. Alliance will ensure the mobile coach is secured (locked) while unoccupied.
- 4. Alliance will be responsible for and ensure documentation is completed under both NRC or state RAM licenses including:
  - a. Dose calibrator (daily constancy, accuracy, linearity and geometry) and PET/CT camera QC in accordance with Alliance procedures
  - b. End of day surveys to include PET/CT coach and state approved client injection rooms
  - c. Radio pharmaceutical ordering and receipt records
  - d. Radioactive disposal records
  - e. Patient dose records
- 5. While on site, radiopharmaceutical doses will be delivered directly to the coach and secured in the on board hot lab. This will ensure the security and safe keeping of radioactive materials.
- 6. The Alliance Authorized User will retain authority and control over patients being injected on the mobile coach or state approved client injection rooms.
- 7. An Alliance Authorized User will be immediately available in person or by telephone to the PET/CT technical staff to answer patient related questions
- 8. F-18 FDG will be supplied as a unit dose and may be ordered by the PET/CT technical staff as prescribed by the authorized

#### NORTHCREST MEDICAL CENTER

Authorized Signature	Date		
Printed Name:			
Title:			9
FOR CONTRACTS USE ONLY:			
Contract #: 007612	Customer #: 24244	Client Type: Hospital	
DO: Darrin McCall	Requestor: Michael Dou	gherty	

## () ALLIANCE HEALTHCARE SERVICES

#### POSITRON EMISSION TOMOGRAPHY/COMPUTED TOMOGRAPHY (PET/CT) MASTER SERVICES AGREEMENT

This POSITRON EMISSION TOMOGRAPHY/COMPUTED TOMOGRAPHY ("PET/CT") Master Services Agreement (the "Agreement") is made effective as of the date fully executed below between Alliance HealthCare Services, Inc., a Delaware corporation, d/b/a Alliance Imaging, located at 100 Bayview Circle, Suite 400, Newport Beach, California 92660 ("Alliance") and NorthCrest Medical Center, a Tennessee not for profit corporation, located at 100 Northcrest Drive, Springfield, Tennessee 37172 (the "Client").

- 1. UNIT LOCATION (the "Unit Location"). If no address is listed in this Section, the Unit Location address shall be Client's address that is listed above.
- UNIT DESCRIPTION: mobile PET/CT system (or a reasonably comparable system).
- 3. FEES.

The fees exclude radiopharmaceuticals.

FLAT DAILY FEE.

Five (5) hour half day of service

\$3,000

Radiopharmaceutical charge per dose

\$150

Hourly overtime beyond five (5) hours that an Alliance technologist is present at the Unit Location

\$300

- a) PET/CT Procedure Schedule and Radiopharmaceuticals. Client shall, no later than 11:00 p.m. each business day, provide to the designated Alliance representative a written schedule of its Radiopharmaceutical requirements for the next business day, showing times and quantities. Client may cancel without financial obligation any prescheduled doses by notifying Alliance's supplier of radiopharmaceuticals at least one (1) business day prior to shipment and such shipment does not occur. In the event that a scheduled procedure cannot be completed due to the actions of Alliance, the costs for the prescheduled radiopharmaceutical shall be borne by Alliance. In the event that the scheduled procedure cannot be completed due to the actions of the Client employees, the cost of the prescheduled radiopharmaceutical shall be borne by the Client at a rate of \$150 per dose, in the event that the scheduled procedure cannot be completed due to the "no show" or patient cancellation at the time of the procedure, the cost of the radiopharmaceutical shall be borne by the Client at a rate of \$150 per dose, provided, however, Alliance agrees not to charge Client for up to one (1) "no show" or patient cancellation FDG charge per month. Above stated fees are for FDG doses up to 15mCi. If the base dose 15mCi price to Alliance increases by ten percent (10%) or more, the cost in excess of ten percent (10%) shall be charged to Client on a dollar-for-dollar basis. Client and shall be responsible for material damages, normal "wear and tear" excepted.
- 4. SCHEDULING. Alliance shall make the Unit available to the Client and any services that Alliance is obligated to provide under this Agreement, and Client agrees to accept the Unit and any such services, one half (1/2) day per week, five (5) hours per day. Alliance shall determine the specific service schedule.
- 5. TERM. The initial term of this Agreement shall be for twenty-four (24) months commencing upon delivery of the Unit to Client (the "Commencement Date") anticipated to be on or about August 2013. Fees under this Agreement shall begin to accrue on the Commencement Date. After the initial term, this Agreement shall automatically renew for successive terms, each of which shall be equal to the length of the initial term, unless either party notifies the other-to-the-contrary in writing at least-one hundred eighty (180) days prior to scheduled expiration. This Agreement shall not automatically renew.

6. INCORPORATION. This Agreement shall consist of the following documents: (1) the cover page(s) to this Agreement; and (2) General Terms and Conditions, which is attached hereto and incorporated herein.

Alliance and Client have duly executed this Agreement as of the last date written below.

ALLIANCE HEALT	ICARE SERVICES, INC.	NORTHCREST MEDICAL CENTER
d/b/a ALLIANCE I	VACING	
Syl	16	Authorized Signature
Authorized Signature Richard W. Johns	/	Printed Name: Randy Davis
	and Corporate Secretary	Title: Sr v B
Date:	17101115+ G17013	Date: 7/80/13 Telephone No. 6/5-399-/601
Telephone No.	(949) 242-5300 33-0239910	Federal Tax (D) No. 62 - 1646 - 85

# S ALLIANCE HEALTHCARE SERVICES

FOR COMER WITE HER ON	VI V.	Out- its I		
FOR CONTRACTS USE OF	Customer #.	24244	Client Type: Hospital	
DirSoles/East:	SDO/East: TGaston	DO: Darrin McCall	Requestor: Michael Dougherty	

A fully executed document must be received prior to service commencement.

To Mail a Signed Document: Alliance HealthCare Services, Inc., ATTN: Contracts Administration Department, 100 Bayview Circle, Suite 400, Newport Beach, California 92660.

To Emall a Signed Document: Contracts@allianceimaging.com

To Fax a Signed Document: 602-345-7637

# ALLIANCE HEALTHCARE SERVICES

#### GENERAL TERMS AND CONDITIONS

EQUIPMENT AND SERVICES.

1. 1.1 The Unit. Alliance shall provide a PET/CT system described in the cover page(s) to this Agreement (the "Unit"). If the Unit described is deemed in Alliance's discretion to be unavailable, a reasonably comparable Unit may be substituted.

1.2 Personnel,

a) Provision of Personnel. Alliance shall provide the services of technical personnel to operate the Unit and a patient coordinator to assist the technical personnel in the operation of the Unit,] as appropriate for Client's procedure volume. Alliance shall ensure that all services provided by Alliance's personnel shall be within the scope of his/her respective duties. Nothing in this Agreement shall be construed to obligate Alliance to violate any applicable employment laws or regulations, and Alliance personnel shall be entitled to take all breaks as required under any applicable laws or regulations,

b) Non-Solicitation, Client agrees not to hire or contract with any Alliance employee during the term of this Agreement, including renewals, and for a period of one (1) year after services cease (collectively, the "Non-Solicitation Period"), without Alliance's prior written consent. Alliance and Client hereby agree that in the event of a breach of this provision damages shall be difficult to calculate and therefore agree Alliance shall be entitled to receive six (6) times the monthly average salary of such employee for the past twelve months (or such shorter period as the employee may have been employed by Alliance). Alliance and Client agree that the aforementioned amounts are reasonable and

shall constitute liquidated damages and not a penalty.

c) Disclosure of Personnel Information. Notwithstanding anything to the contrary in this Agreement, Client agrees, for as long as Alliance remains a Joint Commission-accredited organization, that Client shall not need to independently verify, and shall not require any oral information or written documentation concerning the credentialing, education, training, evaluation, or competencies related to any of Alliance's technical personnel beyond the following, which documentation set composition may be following, which documentation set composition may be modified from time-to-time by Alliance in its reasonable discretion and which Alliance will provide to Client in writing upon request: (a) a description of the competencies related to Alliance's technical personnel who provide services on the Unit; (b) copies of any licenses and certifications for such personnel; (c) evidence that all vaccination test(s) required by applicable State law or regulation have been taken by such personnel; (d) a job description for the technologist(s) providing services on the Unit; and (e) a letter from Alliance's Vice President of Human Resources or designee attesting that criminal investigation background checks have been performed for each of Alliance technical personnel who provide services on the Unit and that such personnel meet the requirements to be employed by Alliance. Alliance shall not be obligated to provide any background check report, drug test report or result, or Job performance evaluation for any of Alliance's technical personnel. Further, notwithstanding anything to the contrary in this Agreement, in the event of a Joint Commission survey of Client, Alliance, upon request by the Joint Commission surveyor, shall have the personnel file of Alliance's technical personnel accessible to the surveyor only for review as may be required by the Joint Commission.

Confidentiality of Information. Client acknowledges that all verifications, documents, electronic data, and other materials concerning

Alliance personnel that Alliance provides or makes accessible in connection with this Agreement (collectively, "Confidential Personnel Information") are valuable property of Alliance, and Client undertakes that, during the term of this Agreement and thereafter until such time that the Confidential Personnel Information otherwise becomes publicly available other than through breach of this Section, Client shall: (i) treat the Confidential Personnel Information as trade secret and confidential assets of Alliance's business; (ii) not disclose (directly or indirectly, in whole or in part) the Confidential Personnel Information to any third-party except with the prior written consent of Alliance or when and if properly disclosed in connection with the Centers for Medicare and Medicaid Services ("CMS"), The Joint Commission, or other applicable federal and state compliance surveys, audits, reviews and record requests or as required by law; (iii) not use (or in any way appropriate) the Confidential Personnel Information for any purpose other than compliance with CMS, The Joint Commission, or other applicable federal and state requirements and/or as required by law; (iv) limit the dissemination of and access to the Confidential Personnel Information to Client's officers, managers, employees, agents, attorneys, consultants, professional advisors or representatives on a need to know basis as may reasonably be required for the performance of Client's compliance obligations outlined above, provided Client ensures that such individuals and entities observe all the confidentiality obligations set forth in this Section; (v) be entitled to use the Confidential Personnel Information only in good faith for the legitimate conduct of its business activities, and shall not in any case use such Confidential Personnel Information to gain a competitive advantage or for purposes unrelated to compliance with CMS, The Joint Commission, or other applicable federal or state requirements; and (vi) return any and all Confidential Personnel Information to Alliance promptly upon the termination or expiration of this Agreement, including but not limited to all such materials, documents, information and electronic data, regardless of how stored or maintained, and including all originals and copies.

1.3 Maintenance. Alliance shall use reasonable efforts to cause the Unit to be maintained in good operating condition. Alliance may do so through the purchase of a maintenance contract from the Unit manufacturer or otherwise, in its discretion. Client shall be responsible for maintaining in good and safe working order any equipment, including but not limited to a gurney or wheelchair, that Client provides to Alliance for Alliance's use under this Agreement.

SCANNING ACTIVITIES.

2.1 Unit. Client shall prepare and maintain a safe and suitable site for the Unit which complies with the manufacturer's specifications (which shall be provided by Alliance) and all applicable laws and regulations. All site costs (for example, costs of tractor/trailer access and egress, power and telephone expenses) shall be Client's responsibility. The Unit Location shall be as referenced in the cover page(s) to this Agreement. Client represents and warrants to Alliance that it currently owns or has authorization to site the Unit at the Unit Location. Further, Client further warrants and agrees that, at all times during the term of this Agreement, Client shall maintain the authorization or ownership to site the Unit at the Unit Location. Client shall indemnify and hold Alliance harmless from any damages or liability arising out of breach of the representations and warranties in this Section. Client may request in writing to Alliance that the Unit Location be

# ALLIANCE HEALTHCARE SERVICES

moved, in which case any such move shall be subject to Alliance's prior approval; all of the obligations under this

Section shall apply to the new Unit Location.

2.2 Power. Client shall provide electrical power to the Unit, including a dedicated power line with 200 amps and 480 volts of three-phase power. Client shall provide the power line, a lockable disconnect box and receptacle within twentyfive (25) feet of the electrical receptacle on the Unit. Notwithstanding anything to the contrary in this Agreement, Client shall be responsible for the quality of power to the Unit and any damage to the Unit due to power that does not meet such specifications or any other problems with power (e.g., sags or surges). As such, Alliance recommends that Client install a line conditioner or surge protector to prevent any problems with power to the Unit. Client shall promptly report to Alliance any problems with power to the Unit.

2.3 Phone and Connectivity. Client shall provide the Unit with a voice telephone line, a dedicated fax compatible telephone line and a RJ-45 ethernet broadband line with an automatic IP address assignment using Dynamic Host Control Protocol ("DHCP") and a proxy-less connection to the

2.4 Operation. The Unit shall be operated only by employees or subcontractors of Alliance. Notwithstanding anything to the contrary in this Agreement, Client shall not be entitled to use the Unit, directly or through a subcontractor, during any period of suspension of this Agreement, following termination of this Agreement, or following expiration of this

Agreement.

Medical Director. Client shall appoint a qualified and licensed physician to act as Medical Director hereunder, along with another such physician to act in his absence (the "Medical Director"). Client shall ensure that all orders for diagnostic procedures under this Agreement are made only by a licensed physician or another licensed healthcare provider authorized by applicable federal and/or state law. Client shall be solely responsible for all activities which constitute the practice of medicine (for example, providing medical advice to patients in connection with PET/CT procedures and the supervision of the injection of radiopharmaceutical agents). Client shall obtain any written consents from patients that are required by the USFDA, state or local law or prudent medical practice. Alliance shall be entitled, but not obligated, to use its own patient consent and screening questionnaire forms to supplement patient forms provided by the Client. Client shall have full responsibility for all medical care, supervision services, and advice provided to patients, in accordance with applicable laws, rules and regulations. All medical care shall be provided under the ultimate supervision of the Medical Director.

2.6 Medical Supplies; Hazardous Waste Disposal; Emergency Care. Client shall provide all medical supplies which may be required (including film and film processing, gowns, medications and radiopharmaceutical agents). Client agrees to dispose of all hazardous waste relating to the services under this Agreement that Alliance provides to Client from time-to-time. Client shall ensure the immediate availability at all times of equipment and personnel to treat patients who require emergency or other medical care (including a cardiac monitor, a fresh oxygen supply, an

aspirator and a defibrillator)

2.7 Patient Handling. Client shall be responsible for the prompt and orderly pick up and delivery of patients to and from their rooms or other designated areas.

2.8 Patient Log. Alliance shall maintain a log of all procedures performed on the Unit. Client shall be provided with copies of the log upon request.

2.9 Modifications. Client shall not modify or alter the Unit without Alliance's prior written consent. Client shall not allow any portion of the Unit to become permanently attached to real property. Client agrees that, upon request, Client shall sign any documents (e.g., a UCC financing statement) evidencing a first priority security interest, mortgage, or assignment in favor of any company (e.g., the original equipment manufacturer) providing financing to Alliance for the Unit. Nothing in this Section, shall affect any ownership interest that Client has in its own property.

2.10 Scheduling. Client shall use all reasonable efforts to schedule its patients consecutively from the beginning of each service day to minimize unutilized scanning time and to prescreen patients for conditions unsuitable for PET/CT procedure. Notwithstanding anything to the contrary in this Agreement, Alliance reserves the right to release its technical personnel and/or Unit from Client's Unit Location after the completion of the last scheduled procedure on any given service day in which no more patients are scheduled provided the technologist(s) have verbally confirmed with the Client that no additional patients shall be added to the schedule for that particular service day.

2.11 Notification of Physicians. Client shall notify its staff of physicians of the availability of the Unit and shall use reasonable efforts to educate the community about the

Unit.

2.12 Exclusivity. Client agrees to use Alliance solely for all of its PET/CT and PET needs, except for an emergency where the use of Alliance's service is impractical, when the patient expresses a desire to receive PET or PET/CT services from a different provider, when the patient's insurance determines that the patient must receive PET or PET/CT services from a different provider, or when the referral is not in the best medical interest of the patient in the physician's judgment. Client, on behalf of itself, its parent, its subsidiaries, owners and/or corporate affiliates (including but not limited to any entity in which Client has an ownership interest) agree during the term of this Agreement, not to own, permit, lease, manage, or invest in any PET/CT or PET system or engage any entity besides Alliance to provide Client with PET/CT or PET services. Notwithstanding anything to the contrary in this Agreement, this Section shall remain in effect during any period in which the Agreement is suspended. Further, in the event this Agreement terminates due to a Client default under this Agreement, this Section shall survive such termination and remain in effect for the remainder of the then-current term of the Agreement had the Agreement not early terminated.
2.13 Access to Records. If the value or cost of

services rendered pursuant to this Agreement is \$10,000 or more over a 12-month period, in accordance with Section 1861(v)(1)(1) of the Social Security Act, Alliance agrees that until the expiration of four (4) years after the furnishing of services under this Agreement, Alliance shall make available, upon written request by the Secretary of the U.S. Department of Health and Human Services, or upon request by the Comptroller General of the United States, or any of their duly authorized representatives, such contracts, books, documents, and records of Alliance that are necessary to certify the nature and extent of such costs. If Alliance carries out any of the duties of this Agreement through a subcontract with another organization and the value or cost of such subcontracted services is \$10,000 or more over a twelve (12) month period, such subcontract shall contain a clause to the same effect as

this provision.

2.14 Licenses. Client shall obtain and maintain all required licenses and regulatory approvals necessary to operate the Unit at Client's premises. Alliance shall reasonably

# ALLIANCE HEALTHCARE SERVICES

cooperate to assist Client to obtain such licenses and approvals. Alliance will possess all necessary State and federal radioactive materials licenses. Alliance will adhere to all licensing requirements applicable to radioactive materials and will be responsible for the safe and proper use of radioactive materials in compliance with applicable laws.

2.15 Taxes. All taxes, if any (for example, sales, use or similar taxes), on the services hereunder shall be the responsibility of Client (other than taxes on Alliance's net

income from the services hereunder).

2.16 Professional Interpretations. Client shall need to engage a radiologist to provide interpretations of PET/CT procedures for Client patients. Alliance shall not be responsible for providing any such interpretations.

2.17 Patlent Records. Client shall maintain patient records for each patient who receives procedures performed

under this Agreement.

2.18 Customer Support. Alliance shall provide the

following:

a) Radiopharmaceuticals. Assistance to Client in obtaining, licensing and handling procedures for

radiopharmaceuticals.

- b) Billing, Information regarding PET/CT billing codes, information and reimbursement data provided, however, that Client shall not be entitled to rely upon any such information by Alliance and shall confirm such information independently by contacting either the local Medicare carrier/intermediary, or seeking the advice of legal counsel or a reimbursement consultant. Client agrees to comply with relevant billing and documentation requirements.
- FEES AND BILLING. Client shall pay Alliance fees that are set forth in the cover page(s) to this Agreement.
  All fees for a billing period shall be due and payable within fifteen (15) days of the last day of such period. Alliance shall invoice Client once each month. Client shall pay a late fee of one and one-quarter percent (1 ½ %) or the maximum legal rate, whichever is less, on all balances outstanding more than fifteen (15) days beyond the due date compounded and assessed for each month that such balances are past due, Alliance may adjust fees effective on each anniversary of the Commencement Date by the percentage increase for the Medical Care Services component of the Consumer Price Index for all Urban Consumers (CPI-U) as recorded by the Department of Labor Index for the then most recently available twelve month period. Client shall be responsible for all billings to Client patients and/or third party payors for PET/CT procedures performed on the Unit. Client's obligation to pay Alliance compensation in accordance with the provisions of this Agreement shall not be dependent upon Client's billing and collection of patient and/or third party payor accounts receivable. Alliance shall not bill, and Alliance shall not cause bills to be submitted to, any patient or third party payor for PET/CT procedures performed on the Unit. All billings for Client patients shall be in the name of Client, and Client shall not subcontract any of the services under this Agreement or the Unit to any third party. Both parties agree that Alliance is providing its services set forth on this Agreement "under arrangement" with Client, such that upon Client's receipt of payment from the Medicare program for PET/CT procedures performed in the Unit, the liability of the beneficiary or any other person to pay for such services shall be fully discharged.
- 4. TERM. The term shall be as specified in the cover page(s) to this Agreement. The term of the Agreement shall also be extended coterminously with any period(s) services are

suspended. In the event this Agreement terminates or expires and Client continues to accept services, the terms and conditions of this Agreement shall apply to the provision of services and Client shall be bound to accept such services until and unless Client shall terminate such extension upon further written notice to Alliance of not less than ninety (90) days. During any such term extension, the fees paid to Alliance shall be increased 10%.

5. SCHEDULING. Alliance shall make the Unit available to Client according to the schedule specified on the cover page(s) to this Agreement. Alliance personnel will not be available during the following holidays observed by Alliance: New Years Day, Memorial Day, Fourth of July, Labor Day, Thanksgiving Day, and Christmas Day. The day of service begins upon initiation of the setup procedures for the Unit and ends upon completion of the shutdown procedures for the Unit.

## 6. INSURANCE, INDEMNIFICATION.

6.1 Insurance.

a) Alliance. Alliance shall maintain insurance covering all risks of physical loss or damage to the Unit, comprehensive general liability and professional liability covering the conduct of its employees, all in amounts and subject to deductibles that are customary in the industry.

b) Client. Client shall maintain comprehensive general and professional liability insurance covering the Client, its employees, staff and physicians and shall require the Medical Director and other physicians who interpret or report on procedures performed on the Unit to maintain professional liability insurance. All such insurance shall be in amounts and with deductibles that are customary in the industry. Client shall bear the risk of loss or damage to the

Unit from Client's negligent actions or omissions.

6.2 Indemnification. Each party hereto shall indemnify and hold the other party harmless from and against any and all liability, loss, damage, cause of action, cost or expense (including reasonable attorney's fees) arising out of, or in any way connected with, any negligent or intentional act or failure to act, any breach of any representation or warranty under this Agreement, or any other wrongful conduct by the respective party, its members, agents, employees or subcontractors in the performance of its duties under this Agreement. The parties agree that upon receipt of a claim or demand for which a party is entitled to indemnification, the indemnified party shall; (i) provide the indemnifying party with prompt written notice of any indemnifiable claim; (ii) permit the indemnifying party to assume sole control of the defense with counsel selected by the indemnifying party; (iii) furnish the indemnifying party with all documents and information within the possession, custody, or control of the indemnified party relating to such claim; (iv) reasonably cooperate with the indemnifying party and its counsel; and (v) not enter into any oral or written negotiation, settlement, or compromise of any indemnifiable claim without the indemnifying party's prior written consent. In the event the indemnifying party defends the indemnifiable claim, it may do so under a reservation of its rights to cease the defense of the claim at a later date (upon reasonable prior written notice to the indemnified party) in the event it is determined that the indemnifying party has no obligation to defend or indemnify the claim.

7. GENERAL.
7.1 Independence. Alliance is an independent contractor of Client, and this Agreement is a contract for

# **6** Alliance HealthCare Services

services, not a lease. No agency, employment, partnership or joint venture is intended to be created by this Agreement. Neither Alliance nor Client shall take any action or position which is inconsistent with those descriptions of the relationship.

7.2 Remedies. Alliance shall not be responsible for failure to provide services as a result of conditions caused by Client. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, ALLIANCE SHALL NOT BE RESPONSIBLE FOR INDIRECT, INCIDENTAL, PUNITIVE, CONSEQUENTIAL, OR OTHER SPECIAL DAMAGES THAT CLIENT MAY INCUR OR DAMAGES CONNECTION THIS **EXPERIENCE** IN WITH AGREEMENT OR THE SERVICES PROVIDED BY ALLIANCE, HOWEVER CAUSED AND UNDER WHATEVER THEORY OF LIABILITY, EVEN IF ALLIANCE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

7.3 Waiver. No waiver of any provisions of this Agreement or a breach thereof shall be valid or enforceable unless in writing and signed by both parties. The waiver by either party of any breach of any term, covenant, warranty, or condition contained in this Agreement shall not be deemed to be a waiver of any subsequent breach of the same or any other term, covenant or condition contained in this Agreement.

7.4 Notices. All notices required or permitted under this Agreement must be in writing and delivered either by reputable national or international overnight delivery service or by registered or certified U.S. mail (postage prepaid with return receipt requested). The initial addresses of the parties to which notice must be sent are listed on the cover page(s) to this Agreement. Notices to Alliance shall be sent to the attention of General Counsel. If notice is delivered by reputable national or international overnight delivery service, then notice shall be effective one (1) business day after deposit with the carrier. If notice is delivered by registered or certified U.S. mail (postage prepaid with return receipt requested), then notice shall be effective five (5) business days after deposit with the carrier. Either party may change its address for notice by notifying the other by a permitted method of giving notice.

7.5 Governing Law; Venue. The laws of the State of California (without giving effect to its conflicts of law provisions) shall govern all matters arising out of or relating to this Agreement, including, but not limited to, its validity, interpretation, performance, enforcement, and construction. Each party hereto hereby irrevocably and unconditionally: (i) consents to submit to the exclusive jurisdiction of the courts of the State of California, and of the United States, located in Orange County, California for any action, suit, or proceeding arising out of or relating to this Agreement (and each party hereto hereby irrevocably and unconditionally agrees not to commence any such action, suit, or proceeding except in such courts); (ii) waives any objection to the laying of venue of any such action, suit, or proceeding in any such courts; and (iii) waives and agrees not to plead or claim that any such action, suit, or proceeding brought in any such court has been brought

in an inconvenient forum. Agreement; Amendment. Entire Agreement is the parties' entire understanding and supersedes all prior agreements, oral and written, with respect to the subject matter of this Agreement, and no party will be bound by any representation, covenant, term, or condition other than as expressly stated in this Agreement. No statements, promise, or representations have been made by any of the Parties to any other, and no consideration has been offered, promised, expected or held out other than as is expressly provided

herein. This Agreement may not be amended except by written agreement signed by both parties to this Agreement. No handwritten changes to this Agreement shall be enforceable unless such changes are initialed by both parties to this Agreement. This Agreement is binding upon and will inure to the benefit of the parties and their respective heirs, personal representatives, successors, and assigns.

7.7 Successors and Assigns. Alliance may assign this Agreement. Client may not assign this Agreement without the prior written consent of Alliance. Client agrees that this Agreement may be performed, in whole or part, by a parent, subsidiary, or affiliate of Alliance and further consent shall not be required. Alliance may also assign the proceeds of this Agreement. Client shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, sale of property or stock, liquidation, or otherwise) to all or a substantial portion of its assets, by agreement in form and substance reasonably satisfactory to Alliance, to expressly assume and agree to perform Client's obligations under this Agreement.

7.8 Third Parties. Nothing in this Agreement creates, or will be deemed to create, any third party beneficiaries of or under this Agreement.

7.9 Attorney Fees. In any dispute arising out of this Agreement (whether litigation is involved or not) or in the

event that either party must take action to collect fees or enforce rights, the prevailing party shall be entitled to reimbursement of its expenses, including court expenses and

lawyers' fees.

7.10 Certain Events. Neither party will be responsible for any failure or delay in its performance under this Agreement (other than financial obligations including payment of amounts due) if such failure or delay is the result of any: labor dispute; act of God; inability to obtain labor or materials; accident; future law, regulation, ordinance or requirement of any government or regulatory agency; or any other event which is beyond its reasonable control.

7.11 Confidentiality. Client acknowledges and agrees that this Agreement is highly confidential and proprietary to Alliance and Client agrees that neither it, nor any of its employees, contractors, or physicians, shall disclose in any manner the terms, provisions, pricing or any other information contained in this Agreement (or any related proposal) to any third party. Further, Client shall ensure that neither it nor any of its employees, contractors, or physicians disclose any of Alliance's policies, procedures, or other confidential information that Client or its employees, contractors, physicians receives, except to the extent required by an accreditation organization to which Client is subject or a governmental entity.

7.12 Accreditation. Alliance and Client agree to set standards of care and quality that comply with the Joint Commission and the American College of Radiology (ACR). Alliance and Client shall reasonably cooperate in all phases of applying, scheduling, preparing and executing surveys or inspections by the Joint Commission and ACR, as needed. Client shall be responsible for costs associated with ACR accreditation. These costs shall include but are not limited to physicist evaluation, phantom hardware and application fees. Alliance shall provide the technical expertise and act as the liaison on Clients behalf to obtain ACR accreditation. Alliance shall comply with ACR guidelines in order to maintain ACR accreditation in good standing. Both parties agree to work reasonably cooperatively to implement changes, correct deficiencies or establish policies required and/or deficiencies or establish policies required recommended by the inspecting agencies as applicable.

# ALLIANCE HEALTHCARE SERVICES

Alliance shall provide Client with a copy of Alliance's Joint Commission accreditation certificate and most current patient satisfaction survey results, as requested by Client.

7.13 Policies and Procedures. Client agrees that Client shall comply with all of Client's policies and procedures, and Client agrees to indemnify and hold Alliance harmless from and against any and all liability, loss, damage, cause of action, cost or expense (including reasonable attorney's fees) arising out of, or in any way connected with, Client's failure to fully comply with Client's policies and

procedures.

7.14 Severability. In the event that any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and the application of such provision to other persons or circumstances shall be interpreted so as reasonably to effect the intent of the parties hereto. The parties hereto further agree to use their commercially reasonable efforts to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.
7.15 Credit Checks. By signing the cover page(s) to

this Agreement, Client hereby authorizes Alliance, as determined necessary by Alliance in Alliance's discretion upon such signature and from time-to-time during the term of the Agreement, to (i) obtain a standard factual credit data report concerning Client through a credit reporting agency or any other similar agency (a "Credit Reporting Agency") chosen by Alliance, and (ii) release to such Credit Reporting Agency any credit applications, financial information, or any other information of Client, Further, Client hereby agrees to provide Alliance with all appropriate credit applications and

paperwork necessary to effectuate the above.

7.16 Construction. Every term and provision of this Agreement is to be construed simply according to its fair meaning and not strictly for or against any party. No provision of this Agreement is to be interpreted as a penalty upon, or a forfeiture by, any party to this Agreement. The parties acknowledge their right to separate legal counsel, and agree to obtain any appropriate advice or opinions about this transaction from their respective counsel. The parties acknowledge that they and their respective legal counsel have had the opportunity to participate equally in the drafting of this Agreement and that in the event of a dispute, no party shall be treated, for any purpose, as the author of this Agreement nor have any ambiguity resolved against it on account thereof.

7.17 Execution. By their signatures on the cover page(s) of this Agreement, each of the signatories to this Agreement represent that they have the authority to execute this Agreement and to bind the party on whose behalf their execution is made. This Agreement constitutes the legal, valid and binding obligation of the parties enforceable in

accordance with its terms.

7.18 Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Delivery of an executed counterpart of this Agreement may be made by facsimile or other electronic transmission. Any such counterpart or signature pages sent by facsimile or other electronic transmission shall be deemed to be written and signed originals for all purposes, and copies of this Agreement containing one or more signature pages that

have been delivered by facsimile or other electronic transmission shall constitute enforceable original documents. As used in this Agreement, the term "electronic transmission" means and refers to any form of communication not directly involving the physical transmission of paper that creates a record that may be retained, retrieved and reviewed by a recipient of the communication, and that may be directly reproduced in paper form by such a recipient through an automated process.

#### TERMINATION.

#### 8.1 Termination.

a) Material Breach. Alliance or Client may terminate this Agreement if the other party breaches any material covenant, term or provision of this Agreement and the material breach is not cured within sixty (60) days following provision of notice to the breaching party specifying the alleged material breach.

b) Bankruptcy. Alliance or Client may terminate this Agreement if the other party commits or suffers (voluntarily or involuntarily) an act of bankruptcy, receivership, liquidation or similar event.

8.2 Termination, Alliance. Alliance may terminate

this Agreement or suspend service if:

a) Payment Default. Client fails to make any payment to Alliance when due and such failure continues for ten (10) days following notice to Client. In the case of any payment default, Alliance may, without notice, cease providing services hereunder after three (3) days following a payment due date should it feel insecure with respect to Client's ability or willingness to make payment,

b) Inability to Cover Costs. Alliance is unable to cover its costs on the services provided hereunder, provided that the parties have negotiated in good faith to modify the terms of this Agreement to eliminate such inability and a period of sixty (60) days has elapsed since Alliance originally notified Client of such condition. In lieu of termination, Alliance may reduce the number of days of service provided.

c) Mobile Route. Alliance's mobile route for service on the Unit to all Alliance clients (including but not limited to Client) should fall below four full days of

contracted service per week.

8.3 Default, In the event that this Agreement terminates due to a default by Client under Section 8.1(a), Section 8.1(b), Section 8.2(a), or Section 9.4 of this Agreement, Alliance may take any action at law or in equity, including, but not limited to, collecting from Client payments then due and to become due under the remaining term of the Agreement had the Agreement not early terminated. The foregoing remedies are in addition to any provided by law. Neither party shall have obligation to exercise any remedy and the exercise of the remedy shall not release the parties for any obligation hereunder. All remedies shall be cumulative, and action on one shall not constitute an election or waiver of any other right to which either party may be entitled.

8.4 Inability to Cover Costs. Client may terminate this Agreement if Client is unable to cover its direct costs (i.e., the fees Client pays to Alliance hereunder) on the aggregate services provided hereunder to all of Client's patients measured over a three (3) month period, provided that: (i) Client notifies Alliance of such inability; (ii) Client provides Alliance with documented proof of Client's inability to cover Client's direct costs over the three (3) month period immediately preceding such provision of notice to Alliance (i.e., a spreadsheet listing, for each procedure provided by Alliance under this Agreement for which Client has during received reimbursement from the payor

# ALLIANCE HEALTHCARE SERVICES

aforementioned three (3) month period, (a) the name of the patient, (b) the date of service, (c) the fee paid to Alliance, (d) the CPT code billed, (e) the name of the payor, (f) the claim submission date, (g) the claim payment date, and (h) the amount received from the payor); and (iii) Client and Alliance have negotiated in good faith to modify the terms of this Agreement to eliminate such inability to cover Client's direct costs and a period of sixty (60) days has elapsed since Client originally notified Alliance of such inability. The direct costs of procedures provided hereunder that have not been separately reimbursed by a payor (e.g., claims not billed, pending claims, procedures subject to DRG, etc.) shall not be included in the calculation to determine whether Client has been unable to cover its direct costs. During the aforementioned sixty (60) day period, Client agrees to make available to Alliance upon request access to Client's books and records to substantiate the data included in the aforementioned spreadsheet. The termination of this Agreement shall not discharge Client from any liability associated with services rendered prior to the termination of this Agreement. Client agrees that at the time of termination, all balances owed Alliance must be paid in full.

COMPLIANCE WITH LAWS.

9.1 Compliance with Current Laws. The parties agree that it is their understanding and intent that this Agreement, including any exhibits and other attachments, complies as of the effective date hereof with all applicable federal and state laws and regulations, including, but not limited to, self-referral and anti-kickback laws. Further, the parties agree that they shall comply with all such laws and regulations, as may be amended from time to time. Client represents and warrants that it has not relied on any billing or reimbursement advice that it may have directly or indirectly received from Alliance, and that Client has and shall consult with Client's own billing and reimbursement experts and attorneys with respect to billing under this Agreement. Further, Client warrants and agrees that, throughout the term of this Agreement, Client shall comply with all applicable billing laws, regulations and rules, as may be amended from time to time.

9.2 No Inducement. This Agreement has been negotiated in good faith through arms length negotiations. Nothing contained in this Agreement, including any compensation paid or payable, is intended or shall be construed: (i) to require, influence or otherwise induce or solicit either party regarding referrals of business, or recommending the ordering of any items or services, of any kind whatevers to the other party or any of its affiliates or to kind whatsoever to the other party or any of its affiliates, or to any other person, or otherwise generate business between the parties, or (ii) to interfere with a patient's right to choose his

or her own health care provider, or with a physician's medical

judgment regarding the ordering of any items or services.

9.3 Change in Law. If any change in any applicable federal, state or local government laws, rules or regulations (each, a "Law" and, collectively, "Laws") would render unlawful the conduct under this Agreement of either party hereto, then the parties shall negotiate in good faith to restructure the business arrangement between the parties to conform with the then existing Laws. If the parties have not reached an agreement regarding the material terms of the restructured business arrangement within forty-five (45) days of the change in such Law or by the effective date of such Law, whichever is sooner, then this Agreement may be cancelled by either party upon thirty (30) days' written notice to the other party or upon such effective date, whichever is sooner.

9.4 No Federal Health Care Program Exclusion. Each party represents and warrants to the other party that: (i) neither the representing party nor any of its officers, directors, or employees or contractors providing services under this Agreement are currently excluded, debarred, or otherwise ineligible to participate in the Federal health care programs as defined in 42 U.S.C. Section 1320a-7b(f) (the "Federal health care programs"); (ii) neither the representing party nor any of its officers, directors, or employees or contractors providing services under this Agreement have ever been convicted of a criminal offense related to health care; and (iii) the representing party is not aware of any circumstances which may result in the representing party or any of its officers, directors, or employees or contractors providing services under this Agreement being excluded from participation in the Federal health care programs. This shall be an ongoing representation and warranty during the term of this Agreement, and each party shall immediately notify the other party of any change in status of the representation and warranty set forth in this Section. In the event a party or any of its officers, directors, or employees or contractors providing services under this Agreement become excluded, debarred, or otherwise ineligible to participate in the Federal health care programs, that party shall be considered in default of this Agreement, and the other party may immediately terminate this Agreement for cause; provided, however, a party can prevent such termination if that party is not excluded, debarred, or otherwise ineligible to participate in the Federal health care programs and immediately terminates its relationship with any of its officers, directors, or employees or contractors providing services under this Agreement who become excluded, debarred, or otherwise ineligible to participate in the Federal health care programs.

[END OF GENERAL TERMS AND CONDITIONS]

Attachment 5.B - Item II.E.(2d.) Fair Value Market Letter April 21, 2015

Jason Evans
Asset Manager
Alliance Healthcare Radiology
Newport Beach, CA 92660

Re: Value of Imaging Equipment

Jason,

As requested, the following is the estimated "Fair Market Value" for imaging equipment described below:

2008 GE Discovery ST 4 PETCT unit housed in an AK Associates Mobile Trailer Fair Market Value: \$225,000

Market value is based on the system and trailer being in good to excellent condition and appearance.

Please contact me if I can be of further assistance.

Sincerely,

Matthew Pac

Vice President

Attachment C.-Need - Item 6.c Hospital Policy

NorthCrest Medical Center				
Policy & Procedure				
TITLE: Emergency Spill Procedures	POLICY NUMBER: MI.RAD.106	PAGE #: 1		
ORIGINAL POLICY DATE: 2000	MOST RECENT REVIEW OR REV	ISION DATE: 4/2014		
INITIATED BY: Medical Imaging Department	GOVERNANCE APPROVAL: Radia	ation Safety Committee		
RELATED STANDARDS:				

#### **POLICY:**

In the event of a radioactive accident, specific procedures shall be followed.

- Minor Spills Involving No Radiation Hazard To Personnel:
  - Notify all other persons in the room at once.
  - Permit only the minimum number of persons necessary to deal with the spill into the area.
  - Confine the spill immediately.
  - Liquid Spills:
    - Wear protective gloves.
    - Drop absorbent paper on spill.
  - Dry Spills:
    - Wear protective gloves.
    - Dampen thoroughly, taking care not to spread the contamination.
    - Notify the Radiation Safety Officer as soon as possible.
    - Decontaminate.
    - Monitor all persons involved in the spill and clean up.
    - Permit no person to resume work in the area until a survey is made and approval of the Radiation Safety Officer is secured.
    - Prepare a complete history of the accident and subsequent activity relating thereto for the laboratory records.
- Major Spills Involving Radiation Hazard To Personnel:

NorthCrest Medical Center				
Policy & Procedure				
TITLE: Emergency Spill Procedures	POLICY NUMBER: MI,RAD,106	PAGE #: 2		
ORIGINAL POLICY DATE: 2000	MOST RECENT REVIEW OR REVISION DATE: 4/2014			
NITIATED BY: Medical Imaging Department GOVERNANCE APPROVAL: Radiation Safety Committee				
RELATED STANDARDS;	1			

- Notify all persons involved in the spill to vacate the room at once.
- If the spill is liquid, and the hands are protected, right the container.
- If the spill is on the skin, flush thoroughly.
- If the spill is on the clothing, discard outer or protective clothing at once.
- Switch off all fans.
- Vacate the room.
- Notify the Radiation Safety Officer as soon as possible.
- Take immediate steps to decontaminate involved personnel, as necessary.
- Decontaminate the areas. (Personnel involved in decontamination must be adequately protected).
- Monitor all persons involved in the spill and clean up to determine adequacy of decontamination.
- Permit no person to resume work in the area until a survey is made and approval of the Radiation Safety Officer is secured.
- Prepare a complete history of the accident and subsequent activity related thereto for the laboratory records.
- Accidents Involving Radioactive Dusts, Fumes, Mists, Organic Vapors And Gases:
  - Notify all other persons to vacate the room immediately.
  - Hold breath and close escape valves, switch off air circulating devices, etc., if time permits.
  - Vacate the room.
  - Notify the Radiation Safety Officer at once.

NorthCrest Medical Center				
Policy & Procedure				
TITLE: Emergency Spill Procedures	POLICY NUMBER; MI.RAD.106	PAGE #: 3		
ORIGINAL POLICY DATE: 2000	MOST RECENT REVIEW OR REVISION DATE: 4/2014			
INITIATED BY: Medical Imaging Department	GOVERNANCE APPROVAL: Radiation Safety Committee			

- Assure that all doors giving access to the room are closed and post conspicuous warnings or guards to prevent accidental opening of doors.
- Report at once all known or suspected inhalations of radioactive material.
- Evaluate the hazard and the necessary safety devices for safe re-entry.
- Determine the cause of contamination and rectify the condition.
- Decontaminate the area.
- Perform air survey of the area before permitting work to be resumed.
- Monitor all persons suspected of contamination.
- Prepare a complete history of the accident and subsequent activity related thereto for the laboratory records.

## Injuries To Personnel Involving Radiation Hazard:

- Wash minor wounds immediately under running water, while spreading the edges of the wound.
- Report all radiation accidents involving personnel (wounds, overexposure, ingestion, inhalation) to the Radiation Safety Officer as soon as possible.
- Call a physician qualified to treat radiation injuries at once.
- Permit no persons involved in a radiation injury to return to work without the approval of the Radiation Safety Officer and the attendant physician.
- Prepare a complete history of the accident and subsequent activity related thereto for the laboratory records.

## Fires Or Other Major Emergencies:

• Notify all other persons in the room and building at once.

NorthCrest Medical Center Policy & Procedure				
MOST RECENT REVIEW OR REVISION DATE: 4/2014				
GOVERNANCE APPROVAL: Radiation Safety Committee				
	POLICY NUMBER: MI.RAD.106  MOST RECENT REVIEW OR REV			

- Attempt to put out fires, if radiation hazard is not immediately present.
- Notify the fire department and other local hospital safety personnel.
- Notify the Radiation Safety Officer.
- Govern fire-fighting or other emergency activities by the restrictions of the Radiation Safety Officer.
- Following the emergency, monitor the area and determine the protective devices necessary for safe decontamination.
- Decontaminate the area.
- Permit no persons to resume work without approval of the Radiation Safety Officer.
- Monitor all persons involved in combating the emergency.
- Prepare a complete history of the emergency and subsequent activity related thereto for the laboratory records.

Attachment 5-Item II.E2(c) Revised Project Costs Chart

## PROJECT COSTS CHART

Α.	Cons	truction and equipment acquired by purchase:	
	1.	Architectural and Engineering Fees	0
	2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	\$35,000
	3.	Acquisition of Site	0
	4.	Preparation of Site	0
	5.	Construction Costs	0
	6.	Contingency Fund	0
	7.	Fixed Equipment (Not included in Construction Contract)	0
	8.	Moveable Equipment (List all equipment over \$50,000)	0
	9.	Other (Specify)	0
В.	Acqui	sition by gift, donation, or lease:	
	1.	Facility (inclusive of building and land)	0
	2.	Building only	0
	3.	Land only	0
	4.	Equipment (Specify) Mobile PET Unit	\$321,360
	5.	Other (Specify) Supplies - Radiopharmaceuticals	\$71,250
C,.	Finan	cing Costs and Fees:	
	1.	Interim Financing	0
	2.	Underwriting Costs	0
	3.	Reserve for One Year's Debt Service	0
	4.	Other (Specify)	00
D.	Estim	ated Project Cost (A+B+C)	\$427,610
E, = 5	CON	Filing Fee	\$3,000
F <u>.</u>	Total (D+E)	Estimated Project Cost  TOTAL	\$430,610

## **AFFIDAVIT**

STATE OF TENNESSEE
COUNTY OF DAVIDSON

NAME OF FACILITY: NorthCrest Medical Center - CN1504-013

I, Kim H. Looney, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 22nd day of April, 2015, witness my hand at office in the County of Davidson, State of Tennessee.

NOTARY PUBLIC

My commission expires <u>January</u> 8, <u>2019</u>

HF-0043

Revised 7/02





# State of Tennessee Health Services and Development Agency Andrew Jackson Building, 9th Floor

www.tn.gov/hsda Phone: 615-741-2364/Fax: 615-741-9884

April 23, 2015

Kim Harvey Looney Waller Landsden Dortch & Davis LLP 511 Union Street, Suite 2700 Nashville, TN 37172

RE:

Certificate of Need Application CN1504-013

Northcrest Medical Center - Initiation of PET Service on Hospital Campus

Dear Ms. Looney,

This will acknowledge our April 22, 2015 receipt of your first supplemental response pertaining to your application for a Certificate of Need for the initiation of a Positron Emission Tomography service (PET) on the Northcrest Medical Center campus at 100 Northcrest Drive in Springfield (Robertson County), Tennessee 37172.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

<u>Please submit responses in triplicate by 4:00 PM, April 28, 2015.</u> If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

## 1. Section B, Project Description, Item I

The explanation for more detail pertaining to the hospital's operation of a mobile PET service without an approved CON during September 2013 to February 2015 is noted.

The applicant states that it had prior approval from the payers, including Medicare and TennCare, to perform all of the PET scans provided. It appears that documentation of CON approval for the mobile PET service may not have been required or covered as a part of the credentialing process between the hospital and all of the payer sources. Please explain how the credentialing process with payers may provide a means to cross check for services requiring approved CONs going forward.

Since it is now understood that an approved Certificate of Need is required to operate a PET service at the hospital in accordance with state law TCA 68-11-1607, please briefly describe any additional actions the applicant has taken to

review its status regarding CON approval for all reviewable equipment and services required under TCA 68-11-1607.

Please also describe actions or plans by NMC executive leadership to notify the payers that the hospital did not have an approved CON to operate a mobile PET service from 9/2013 through 2/2015 for the purpose of cooperating with any requests that may be needed to rectify the matter. In your response, please document the hospital's written notification in this regard, as appropriate.

### 2. Section B, Project Description, Item II.C and Section C, Need, Item 6

The corrected amount indicating that 227 total mobile PET procedures were provided during the 17 month period ending February 2015 is noted (average of 13 per month). Using this rate and adding to the 266 Robertson County resident PET procedures documented in the HSDA Equipment Registry as being performed during the CY2013 period, it appears that the applicant has accounted for approximately 90% of the total projected utilization in Year 1. However, the rationale supporting the 21% increase in volumes in mobile PET procedures from 475 procedures in Year 1 to 573 procedures in Year 2 remains somewhat unclear. Please also discuss the methodology used to project volumes in Year 2 in more detail.

The payer mix table supporting the projected utilization is noted. A comparison to previous mobile PET volumes performed during the September 2013 – February 2015 period would be appreciated. Please complete the table below.

Mobile PET Service Prior Payer Mix, September 2013 - February 2015

Payor Source	# of Mobile PET Scans Performed	PET Service Gross Revenue Amount	as a % of Total Gross Revenue
Medicare			
TennCare			
Managed			
care			
Commercial			
Self-Pay			
Other		·	
Total			

#### 3. Section B, Project Description, Item II.E.

#### Item 2.a. and Item 2.b.

The sites served by the vendor's mobile PET unit during the previous 17 month period that the hospital provided the service are noted. In reviewing the proposed schedule for Thursday afternoon, Friday morning and potentially Monday morning days of operation, it appears that the distances to the Desoto Mississippi and Union City, Tennessee mobile PET sites may impact the ability to expand to more days at Northcrest. In addition to distance, what other factors

must be taken into consideration to determine whether or not an additional mobile PET unit may be necessary in order to implement the schedule desired? If an additional unit is utilized, how might this be reflected in the contractual agreement between the hospital and the vendor? Please clarify.

## 4. Section C. Need Item 1. (Project Specific Criteria - PET Service)

Item 4- The response is noted. With respect to the referral arrangements with Vanderbilt Ingram Cancer Center and Tennessee Oncology, the applicant states that these entities offer chemotherapy services on the Northcrest campus. Since chemotherapy utilization was not noted by the hospital in the most recent final 2013 JAR, please describe the arrangements between the parties and identify the most recent 12 month utilization that applies to this service at the hospital.

**Item 6.c.** – The "Emergency Spill Procedures" recently reviewed in April 2014 is noted. As an additional point of interest, please also briefly describe the responsibilities of the hospital's Radiation Safety Officer such as coordinating activities with first responders and providing notification to the appropriate state, local and federal emergency authorities.

### 5. Section C, Need, Item 3 (Service Area)

The response is noted. The applicant has also clarified that the prior and future utilization of the mobile PET service will include use by residents of Montgomery and Cheatham Counties in Tennessee. As such, it would be helpful to illustrate historical PET utilization by residents of the Secondary Service Area in the table below.

PET Utilization by Residents of Applicant's Secondary Service Area

	2011	2012	2013
Cheatham County			
Resident			
Procedures at all			
TN Provider Sites			
Montgomery			
County Resident			
Procedures at all			
TN Provider Sites			
SSA Resident			
procedure Rate per			
1,000 population			

Sources: HSDA Equipment Registry, TDH population estimates

## 6. Section C, Economic Feasibility, Item 4. (Projected Data Chart)

Per the response provided, thank you for clarifying that the audited Consolidated Statement of Operations contained in the attachments pertains to Northcrest Medical and Affiliates. Of the affiliates noted on page 6 of the Kraft CPA, LLC audited report, reference is made to Northcrest Health Network, LLC (NHN), a nonprofit physician hospital organization. Does the applicant have an ownership relationship with NHN that should be noted as a part of the application (Section A, Applicant Profile, Item 3)? If so, please discuss the

proposed organizational and business relationships among these entities in such a manner that their affiliation with the project can be understood. An organization chart will be helpful.

### 7. Section C., Economic Feasibility, Item 6 B.

The applicant's average charge of \$5,684.00 per PET procedure is different than the \$3,679 average gross charge identified on in the response to Item 5 on page 24 and the \$3,679 average gross charge derived from the Projected Data Chart on page 26 of the application. Please explain the differences between the amounts.

In your response, please compare the correct charge to the range from the HSDA Equipment Registry shown below (as based on provider reports for CY 2013).

PET Average Gross Charge Range, CY 2013

1st Quartile	Median	3rd Quartile
\$3,543.30	\$4,543.25	\$7,302.21

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." For this application the sixtieth (60<sup>th</sup>) day after written notification is June 17, 2015. If this application is not deemed complete by this date, the application will be deemed void. Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the <u>next review cycle</u>, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. 3 68-11-1607(d):

- (1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is

Ms. Kim Harvey Looney April 23, 2015 Page 5

deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please do not hesitate to contact this office.

Sincerely

Health Examiner

Tennessee Health Services & Development Agency

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